Sysmex

OPERATOR'S MANUAL

Automated Blood Coagulation Analyzer

CA-50

CHAPTER 1: INTRODUCTION
CHAPTER 2: ANALYSIS PREPARATION
CHAPTER 3: SAMPLE ANALYSIS
CHAPTER 4: DISPLAY OF ANALYSIS RESULTS
CHAPTER 5: MAINTENANCE & SUPPLIES REPLACEMENT
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SYSMEX CORPORATION
KOBE, JAPAN

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Code No. 461-2035-2
PRINTED IN JAPAN
Date of Last Revision: February 2001

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- The display screens shown in this manual may differ slightly from the actual displays.
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- Patient names and doctor names are entered for information and illustration purposes only, and do not imply real specific persons.

RECEIVING INSTRUCTIONS

The CA-50 has been thoroughly tested before shipment, and has been packaged carefully to prevent damage from shipping and handling. Reagents and options have also been sent and will arrive accompanying the analyzer. Follow these guidelines when the system arrives:

- Check to see that the arrows on the sides of the packages are pointing up. If the arrows do not point up, record this information on the bill of lading.
- Visually inspect the outside of the package for rips, dents, or possible shipping damage. Document any sign of damage on the bill of lading, regardless of how insignificant it may appear. *This is for your protection!*
- Notify your service representative that the CA-50 system and its components have arrived.
- Wait for your service representative to unpack the system and open the packages.
- Follow the unpacking and storage instructions provided on the outside of the package. Special requirements such as refrigeration are clearly marked on the outside of the carton and will be included in the unpacking instructions and package inserts.

WARRANTY INFORMATION

All instruments manufactured by Sysmex® are warranted against defective materials or workmanship for a period of one year commencing on the installation date at the customer's required location.

This Warranty does not cover any defect, malfunction, or damage due to:

1. Accident, neglect or willful mistreatment of the product
2. Failure to use, operate, service, or maintain the product in accordance with the applicable Sysmex Operator's Manual
3. Failure to use the appropriate reagents or chemicals specified for the product

ENSURE SAFE OPERATION OF THE INSTRUMENT

Before operating this instrument, carefully read the "Ensure Safe Operation of the Instrument" and OPERATOR'S MANUAL, and strictly follow the instructions given in them.
This manual carries a variety of illustrations to make sure that the product can be used safely and correctly, thus preventing you and others from suffering injuries and damage to property.
The illustrations and meaning are described in the following.
Do understand what they mean before proceeding to the text of the MANUAL.

Meaning of Signs

WARNING • If this sign is ignored and the instrument is operated incorrectly, there is a potentially hazardous situation which could result in death or serious injury of an operator, or grave property damage.

CAUTION • If this sign is ignored and the instrument is operated incorrectly, there is a potentially hazardous situation which may result in injury of an operator, adverse effect on output, or may cause property damage.

Caution on Diagnosis

CAUTION • This product is a clinical examination instrument for screening. In making clinical judgment based on analysis results, a physician is requested to take clinical examination results and other test results into consideration.

⚠ WARNING

- **In the event the instrument emits abnormal odor or any smoke, turn OFF the power immediately and disconnect the power plug from the wall socket.**
  If the instrument is used continuously in that state, there is a hazard that fire, electrical shock, or injury may result.
  Contact your Sysmex service representative for inspection.

- **Take care not to spill blood or reagent, or drop wire staples or paper clips into the instrument.**
  Those might cause short circuit or smoke emission. If such trouble should occur, turn OFF the power immediately and disconnect the power plug from the wall socket. Then contact your Sysmex service representative for inspection.

- **Do not touch the electrical circuits inside the cover. Especially if your hands are wet, there is a hazard that electrical shock may result.**

- **During an analysis, do not open the pipette guide and put in hands or fingers. That could cause injury. When the pipette guide is opened during an analysis, an alarm sounds and the operation stops.**

- **Always wear rubber gloves when performing maintenance work or inspection. Use specified tools and parts.**
  After work is over, wash your hands with disinfectant.
  There is a possibility that those areas of your hands which came in contact with blood could suffer infection.

- **Be careful when handling samples**.
  Always wear rubber gloves; otherwise infection by bacteria could result. If sample splash happened to enter your eye or a cut, wash it off with plenty of water, and immediately see a physician.

When Handling Reagent

- **If a reagent happens to enter your eye, wash it off immediately using plenty of water, and take medical treatment at once.**
- **If you should swallow it inadvertently, call for a physician immediately, drink plenty of water, and throw up.**
- **If it happens to adhere to your hands or skins, wash it off using plenty of water.**

- **When discarding used reaction tubes and instrument consumables, take proper disposing steps as medical, infectious, and industrial wastes.**
  If they are contaminated with blood, infection of bacteria may result.

- **Do not modify the instrument. Its modification is prohibited by Pharmaceutical Affairs Law.**

⚠ WARNING

Power Supply, Connection, and Grounding

- **Never put the power plug in any socket other than the AC 117, 220 or 240 V socket.**
  Otherwise, fire or electrical shock will result.

- **When installing the instrument, be sure to ground it.**
  Otherwise, fire or electrical shock will result.

Handling Power Supply Cord

- **Take care not to damage the power cord, place a heavy device on it, or pull it forcibly.**
  Otherwise, the wire may break causing fire or electrical shock.

- **When connecting the instrument to a peripheral (host computer), be sure to switch OFF the power beforehand**.
  Otherwise, electrical shock or instrument failure may result.

⚠ CAUTION

Use of Reagents

- **After unpacking, be sure not to allow dust, dirt, or bacteria to come in touch with the reagent.**
- **Do not use reagents which have expired.**
- **Handle a reagent gently to prevent formation of bubbles.**
- **Take care not to spill a reagent. If it spills, wipe it off immediately using a wet cloth or the like.**
- **Follow other instructions described on the Package Insert in each reagent.**

Use of Instrument

- **When performing maintenance work or inspection, use specified tools and parts. Do not use substitute parts, or modify the instrument. It is hazardous.**
- **Those who have no or only limited experience in using instrument are recommended to have guidance or assistance of those with sufficient experience.**
- **If the instrument has developed a trouble by any chance, a person in charge of it should take steps within the range specified in the OPERATOR'S MANUAL. As to troubles other than mentioned, contact your Sysmex service representative for assistance or service.**
- **Unpacking, installation, and confirmation of initial setup must be done by your Sysmex service representative.**

Environment for Use

- **Install the instrument in a place which is not subject to water splash.**
- **Install the instrument in a place which is not subject to adverse effects of high temperature, high humidity, dust, direct sunlight, strong lighting, etc.**
- **Do not give the instrument a strong vibration or impact.**
- **Do not install the instrument near a chemical storage or a place where a gas is generated.**

Recommended Pipette and Pipette Chip

- **We recommended that you use the following pipettes and pipette chips to add plasma and dispense/add reagents.**
  - Pipette: Eppendorf reference 4910 (50 - 200 µL)
  - Pipette Eppendorf 300 µL chip

  For details on the usage of the pipette and pipette chip, refer to the instruction manuals attached to them.

INTRODUCTION

Thank you for purchasing the Sysmex® Automated Blood Coagulation Analyzer CA-50.
Carefully read the OPERATOR'S MANUAL for correct use of the unit.
Keep this MANUAL in good condition after reading. It will continue to be of your help in finding specific information about this instrument.

CONTENTS OF THIS MANUAL

To make full use of the functions of this instrument, thoroughly read this manual and use the instrument as directed. The Operator's Manual is made up of the ten chapters and appendices listed below.

Chapter 1:	Introduction	Provides an overview of the instrument, explaining its equipment, operating procedures, and messages as well as points to be careful about during installation.
Chapter 2:	Analysis Preparation	Explains how to prepare the instrument, reagents, and samples before performing analyses.
Chapter 3:	Sample Analysis	Describes how to analyze samples and explains registration procedures for sample ID numbers and analysis parameters.
Chapter 4:	Display of Analysis Results	Explains the screen displays and the processing of external output.
Chapter 5:	Maintenance & Supplies Replacement	Explains the periodic maintenance procedures and how to replace reagent and other supplies.
Chapter 6:	Quality Control	Explains how to perform quality control analyses and how to print and store quality control data.
Chapter 7:	Setting Standard Curves	Explains how to prepare standard curves.
Chapter 8:	Troubleshooting	Explains the error messages and how to troubleshoot.
Chapter 9:	Functional Description	Explains the coagulation detection principles. Also lists the names and functions of the each parts.
Chapter 10:	Instrument Setup	Explains how to preset the instrument's various settings, such as the data measure settings (including limits that indicate abnormal data) and the test protocol settings.
Appendix A:	Installation	Explains how to install the CA-50.
Appendix B:	Technical Information	Includes data output format for host computer and other reference materials.

PREMISES FOR SIGNS

Meaning of Signs

⚠ **WARNING**	• If this sign is ignored and the instrument is operated incorrectly, there is a potentially hazardous situation which could result in death or serious injury of an operator, or grave property damage.

⚠ **CAUTION**	• If this sign is ignored and the instrument is operated incorrectly, there is a potentially hazardous situation which may result in injury of an operator, adverse effect on output, or may cause property damage.

CAUTION:	• Indicates what we would like you to know to maintain instrument performance and prevent its damage.

NOTE:	• Indicates information which will come handy in operating the instrument.

Document Conventions

In explaining operation, this manual uses the conventions as shown below.

- The keys on the panel keyboard are expressed within square brackets.
  For example: [Start], [Print], [∧]
- The display on LCD appears within quotation marks.
  For example: "PT", "QC"

NOTE:	• LCD and printing described in this manual may differ from those in practice. • As a result of product improvements, details described in this manual may differ slightly from the actual product.

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1. INTRODUCTION

The Sysmex® CA-50 is an automated blood coagulation analyzer *For In Vitro Diagnostic Use* to perform blood coagulation tests in clinical laboratories.

Chapter 1 provides an overview of the instrument and analysis procedures that should be read before the CA-50 is used in a daily routine.
The major elements of Chapter 1 are listed below.

Instrument Overview
Provides an overview of the CA-50's functions.

Analysis Procedure Overview
Provides an overview of the analysis procedure, LCD screen display, and key operation.

Installation Precautions
Explains matters that require confirmation before installing the instrument, such as the installation space, required equipment, and environmental conditions.

Instrument Specifications
Provides the instrument specifications.

Menu Tree
Shows a menu tree of the CA-50.

2. INSTRUMENT OVERVIEW

The CA-50 is an automated blood coagulation analyzer that can quickly analyze samples with a high degree of accuracy. The CA-50 can analyze samples using a Coagulation Method; and the analyzed data can be displayed on its LCD screen and printed by the built-in printer. The CA-50 also has some supplemental functions including quality control.

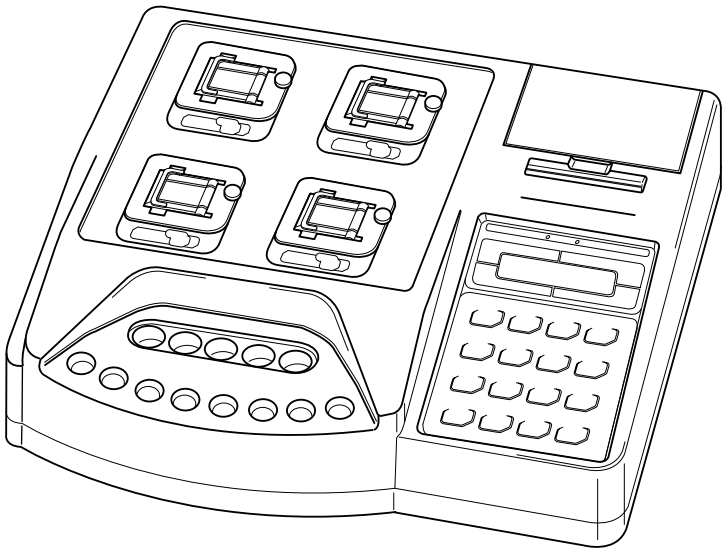


Figure 1-1: Overview of CA-50

3. OUTLINE OF OPERATION

The CA-50 performs an analysis by the following procedure.

Table 1-1: CA-50 Analysis Procedure

Check before turning ON power
Power ON
Self-check
Ready
Preparation for analysis
Work List
Press [START] key
Execution of sample incubation
Addition of reagents
Execution of analysis
Discard used reaction tubes
Ready
Power OFF
Operation after analysis completion

- ▭ : Indicates actions performed by the operator.
- **Ready** : Indicates that the instrument is in the ready status. At this time, the detector LED of each channel will light up in green indicating that you can perform operations such as analysis and settings.

4. ANALYSIS PARAMETERS AND CALCULATION PARAMETERS

The CA-50 can analyze and calculate the parameters shown below. Additional analysis and calculation parameters can be registered as well.

The following list shows the analysis and calculation parameters that can be analyzed by the CA-50.

Table 1-2: CA-50 Analysis Parameters and Calculation Parameters

Method	Analysis parameter	Calculation parameter
Coagulation Method	Prothrombin Time (PT)	Prothrombin Activity Percent
	Activated Partial Thromboplastin Time (APTT)	Prothrombin Ratio
		INR
	Fibrinogen (Fbg)	Derived Fbg
	Thrombotest (TTO)	Fibrinogen Concentration
	Normotest (NT)	Thrombotest Activity Percent
	Thrombin Time (TT)	Normotest Activity Percent
	Extrinsic Factor Deficiency Assay (II, V, VII, X)	Factor II Activity Percent
		Factor V Activity Percent
	Intrinsic Factor Deficiency Assay (VIII, IX, XI, XII)	Factor VII Activity Percent
		Factor VIII Activity Percent
		Factor IX Activity Percent
		Factor X Activity Percent
		Factor XI Activity Percent
		Factor XII Activity Percent

CAUTION • If you analyze with a wrong reagent, correct analysis results will not be obtained.

NOTE: • You can set up to 3 types of calculation parameters each for an analysis parameter.

CAUTION Interpretation of APTT Abnormal Early Reaction.

- APTT results less than or equal to 20.0 seconds, APTT results with NC (No Coagulation), SC (Slight Coagulation) or CCE (Coag. Curve Error) error messages, or abnormally short APTT results may be caused by an abnormal early reaction.
  APTT results with an abnormal early reaction can be identified in the analysis data.
- If an APTT result less than or equal to 20.0 seconds is obtained, the following steps should be taken:

  1. Verify sample and reagent integrity along with maintenance procedures.
  2. Print out the Analysis data.
     See *Chapter 4, Section 4: OUTPUTTING ANALYSIS RESULT and Chapter 10, Section 4.2: Built-In Printer Settings.*
     Note that the stored analysis results will be deleted, when you start a next analysis on the same channel or you turn OFF the power or so on.
  3. Observe time in the "2%" position.
  4. If that time is equal to or less than 15 seconds, then an abnormal early reaction may have occurred.
  5. Re-analyze the sample.
  6. If result is the same, it should not be reported.
  7. Review the previous patient history to determine acceptability of patient results. Results of the other parameters considered, then make overall evaluation.
  8. Follow your laboratory's alternate protocol.

- An error code may or may not be associated with this result.
- An abnormal early reaction rarely occurs.
- The CA-50 should be set up so that any APTT results of less than or equal to 20.0 seconds will have a message of <20.1 seconds on the print-out.
- To set up this function *see Chapter 10, Section 3.4: Report Limit Settings* and enter 20.1 for the APTT lower limit.
- Remember to change the Built-in Printer Settings back to "List" after review of the analysis data.

5. LCD SCREEN AND INPUT KEYS

5.1 LCD Screen

The instrument's status, analysis results, and all other information are displayed on the CA-50's LCD screen. The screen is capable of displaying 16 characters by 2 lines maximum.

Display position of the each analysis channel on the screen

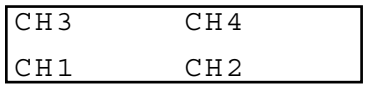


Figure 1-2: Display position of the each analysis channel on the screen

On the Analysis screen, the LCD screen is split into four parts to show the data of respective channels from 1 to 4.
Analysis parameters are abbreviated into two characters as shown below:

- PT: PT
- AP: APTT
- Fg: Fbg
- TO: TTO
- NT: NT
- TT: TT
- F2: Factor II
- F5: Factor V
- F7: Factor VII
- F8: Factor VIII
- F9: Factor IX
- 10: Factor X
- 11: Factor XI
- 12: Factor XII

Settings Screen

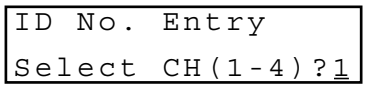


Figure 1-3: Example of Settings Screen

On the Settings screen, parameters to be set or selected are displayed on the upper and lower lines.

5.2 Input Keys

By using the input keys, you can perform each setting such as entering numerals and selecting various parameters.

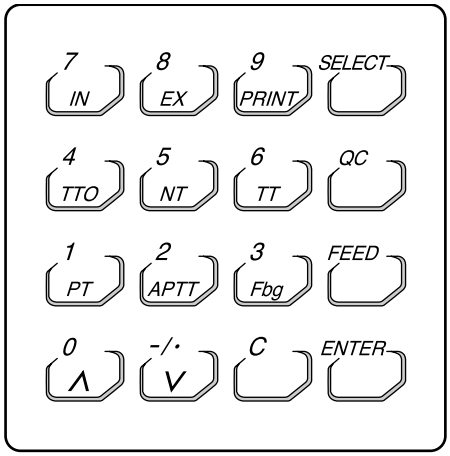


Figure 1-4: Input Keys

Table 1-3: Operation of Input Keys

Key	Operation
1/PT	Press to input the number "1" or select "PT".
2/APTT	Press to input the number "2" or select "APTT".
3/Fbg	Press to input the number "3" or select "Fbg".
4/TTO	Press to input the number "4" or select "TTO".
5/NT	Press to input the number "5" or select "NT".
6/TT	Press to input the number "6" or select "TT".
7/IN	Press to input the number "7" or select "intrinsic factor".
8/EX	Press to input the number "8" or select "extrinsic factor".
9/PRINT	Press to input the number "9" or print a menu.
0/∧	Press to input the number "0", scroll a menu up, or switch to the previous data.
-/./∨	Press to input a hyphen or a decimal point, scroll a menu down, or switch to the next data.
C	Press to clear inputted data or stop an error beep.
SELECT	Press to switch between Menu and Ready, cancel updated data (when confirmed), or return to the previous screen.
QC	Press to input "QC" (when inputting an ID number).
FEED	Press to feed paper.
ENTER	Press to set inputted data or execute updated data (when confirmed).

CAUTION: • When a key has two or more functions, the function will be changed over depending on the situation when the key is pressed.

6. PASSWORDS

Important programs are protected by a password so that the programs can be executed under the control of a supervisor.
When a menu that is protected by a password is to be executed, a Password Entry window will appear. To execute the menu, enter the preset password and press the [Enter] key.
For details on how to set the password, see *Chapter 10, Section 5.4: Password Settings*.

7. ALARMS

The CA-50 makes three types of alarm sounds.

1. Key Entry
   A short beep will sound each time an input key is pressed.

2. Reagent addition timing
   Two short beeps followed by a long beep will sound to let you know the timing of adding reagents.

   The time allowed for reagent addition is preset at 10 seconds as default; 5 seconds before and after the time of addition. If you wish to change the allowed time, see *Chapter 10, Section 3.2: Test Protocol Settings*.

Table 1-4: Reagent Addition Timing Alarm

Reagent addition allowed time (start)		5 seconds before	• • •	Reagent addition	• • •	Reagent addition allowed time (end)
Two short beeps	No sound	A short beep	A short beep	A long beep	A short beep	A long beep
			One beep per second	For 0.5 seconds	One beep per second	An error beep

Allowed time for reagent addition

3. Error
   A long beep will sound when an error occurs on the instrument.
   The beep will continue to sound until the [C] key is pressed.

8. DETECTOR LED

The detector LED of each channel indicates the status as shown in the table below.

Table 1-5: Operation of Detector LED

During warming-up	Ready	During incubation	Reagent addition timing	During photo detection	Ready
Turns off	Lights up in green	Blinks in red	Blinks in green	Lights up in red	Lights up in green

9. PACKAGING

The CA-50 is thoroughly checked before it is shipped from the factory, and is carefully packaged to withstand shocks during shipment.
After the CA-50 has been delivered, check the packaging. Make sure that the instrument is free of exterior damage.
Your Sysmex service representative will unpack and install the instrument after delivery and will also set the initial settings.

10. INSTALLATION ENVIRONMENT

10.1 Installation and Relocation

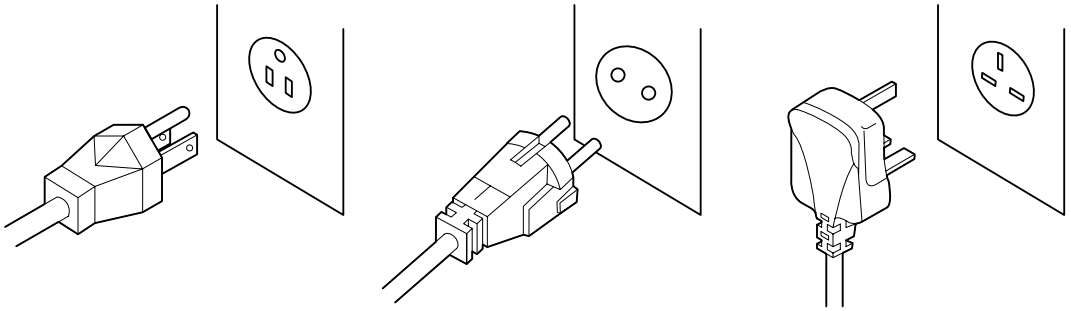
The CA-50 is installed by your Sysmex Service representative. In case relocation becomes necessary after installation, see *Appendix A: INSTALLATION* to install the instrument correctly.

WARNING • When relocating the CA-50, be sure to wear rubber gloves. After the relocation, wash your hands with disinfectant solution.
If your hands are contaminated with blood, infection by bacteria or the like can occur.

CAUTION • When relocating the CA-50, hold the instrument securely. If the instrument falls, you can get injured or the instrument can be damaged.

10.2 Grounding

The instrument power supply cord uses a 3-prong plug. When the power supply socket is 3-prong (with grounded), simply plug it to the socket.



117 VAC Spec. 220 VAC Spec. 240 VAC Spec.

Figure 1-5: Plugs

WARNING • Make sure to ground the instrument. Inadequate grounding could cause electrical shocks.

NOTE: • The number of power supply sockets required is 1.

10.3 Installation Space

To ensure that the instrument fulfills its function, it is important to install it in an appropriate place:

- Select a place that is close to the power supply.
- Secure a place spacious enough for maintenance and service. Giving consideration to heat radiation by the instrument, provide at least 10 cm distance from the wall to the rear panel.

The instrument dimensions are shown below. The power supply cord is 1.8 m long.

Table 1-6: Instrument Dimensions

Width (mm)	Depth (mm)	Height (mm)	Weight (kg)
327	302	113	4.5

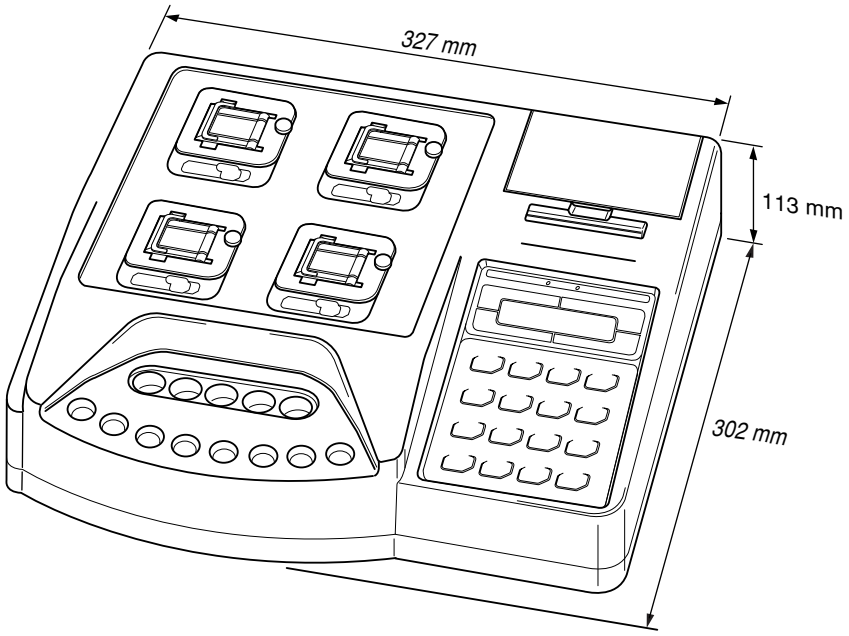


Figure 1-6: Instrument Dimensions

10.4 Installation Environment

- Use the instrument at an ambient temperature of 15°C - 35°C (optimum: 23°C).
- Use it at a relative humidity range of 30% - 85%.
- Avoid a place that can become extremely hot or cold.
- Avoid a place that can be exposed to direct sunlight.
- Choose a well-ventilated place.
- Avoid a place close to a wireless telegraph or communication facility where high frequency waves can be generated or radio interference can occur.
- Do not use in dusty areas.

11. INSTRUMENT SPECIFICATIONS

Analysis parameters/Calculation parameters
See *Section 4: ANALYSIS PARAMETERS AND CALCULATION PARAMETERS* in this chapter.

Simultaneous Random Analysis of 4 Parameters
Random analysis is possible.

Required Sample

Prothrombin Time (PT):	50 µL
Activated Partial Thromboplastin Time (APTT):	50 µL
Fibrinogen (Fbg):	10 µL
Thrombotest (TTO):	20 µL
Normotest (NT):	10 µL
Thrombin Time (TT):	100 µL
Extrinsic Factor Deficiency Assay (II, V, VII, X):	5 µL
Intrinsic Factor Deficiency Assay (VIII, IX, XI, XII):	5 µL

Analysis Principles
Coagulation Method

1. Coagulation Reaction Detection Method (Scattered Light Detection Method)
   Irradiates red light (660 nm) onto a mixture of blood plasma and reagent and detects the change in turbidity (when the fibrin clots are formed) as the change in scattered light. And measures the coagulation time.

2. Coagulation Point Detection Method (Percentage Detection Method)
   Calculates the coagulation time as the time required to achieve the amount of scattered light that is set for the coagulation detection point, using the amount of scattered light that is present just after the start of detection as 0%, and the amount of scattered light that is present at the completion of coagulation as 100%.

Range of Analysis
Fibrinogen Concentration
Can analyze from 50 mg/dL to 450 mg/dL.

Detection Time
Detects within the maximum detection time, and measures the result.
Typical maximum detection time: 100 seconds for PT and Fbg; 190 seconds for others.
Maximum detection time: 600 seconds for each parameter

Reproducibility

Prothrombin Time (PT):	C.V. 2% or less
Activated Partial Thromboplastin Time (APTT):	C.V. 2% or less
Fibrinogen (Fbg):	C.V. 4% or less
Thrombotest (TTO):	C.V. 4% or less
Normotest (NT):	C.V. 4% or less
Thrombin Time (TT):	C.V. 10% or less
Extrinsic Factor Deficiency Assay (II, V, VII, X):	C.V. 5% or less
Intrinsic Factor Deficiency Assay (VIII, IX, XI, XII):	C.V. 5% or less

* The data above are variation coefficients for coagulation times (in seconds) or for the amount of change in activity% taken from 10 analyses of Dade Behring Ci-Trol Level 1 (control plasma), with the reagents below used.

Thromboplastin•C plus
Dade Behring Actin Activated Cephaloplastin Reagent
20 mM Calcium Chloride Solution
Dade Behring Fibrinogen Determination Reagents
Owren's Veronal Buffer
CA Series Complex Factor TTO
CA Series Complex Factor HPT
Dade Behring Factor-deficient Plasma

Display
Displays characters on a liquid crystal display (LCD).

Printing
Permits graphic printing through a built-in printer. (Printer paper specification: F1-1, width: 58 mm)

External Input/Output
Equipped with an RS-232C serial port (bit serial voltage signal).

Detector
Detector: 4 wells (Scattered light detector)

Incubator
Incubator: 5 wells

Reaction Tube Holder
Reaction tube holder: 8 wells

Temperature Control

Detector:	37°C±0.5°C
Incubator:	37°C±1°C

Applies when room temperature is within 15°C - 35°C.

Time to Reach Temperature Setting
Reaches preset temperature within 30 minutes after power is turned ON (when the room temperature is within the specified range).

Quality Control
$\overline{X}$ control (L-J control): 50 points × 3 files, 14 parameters

Standard Curve
6 points, 14 parameters

Power
Rated voltage: 117 VAC±10%, 230 VAC±15%
Frequency: 50 Hz or 60 Hz
Power consumption: 90 VA or less
Temperature Compensation Required: Approx. 307 BTU/h (77 kcal/h)

Environmental Requirements
15°C - 35°C

Dimensions/Weight
Main Unit: 327 (W) × 302 (D) × 113 (H) mm; approx. 4.5 kg

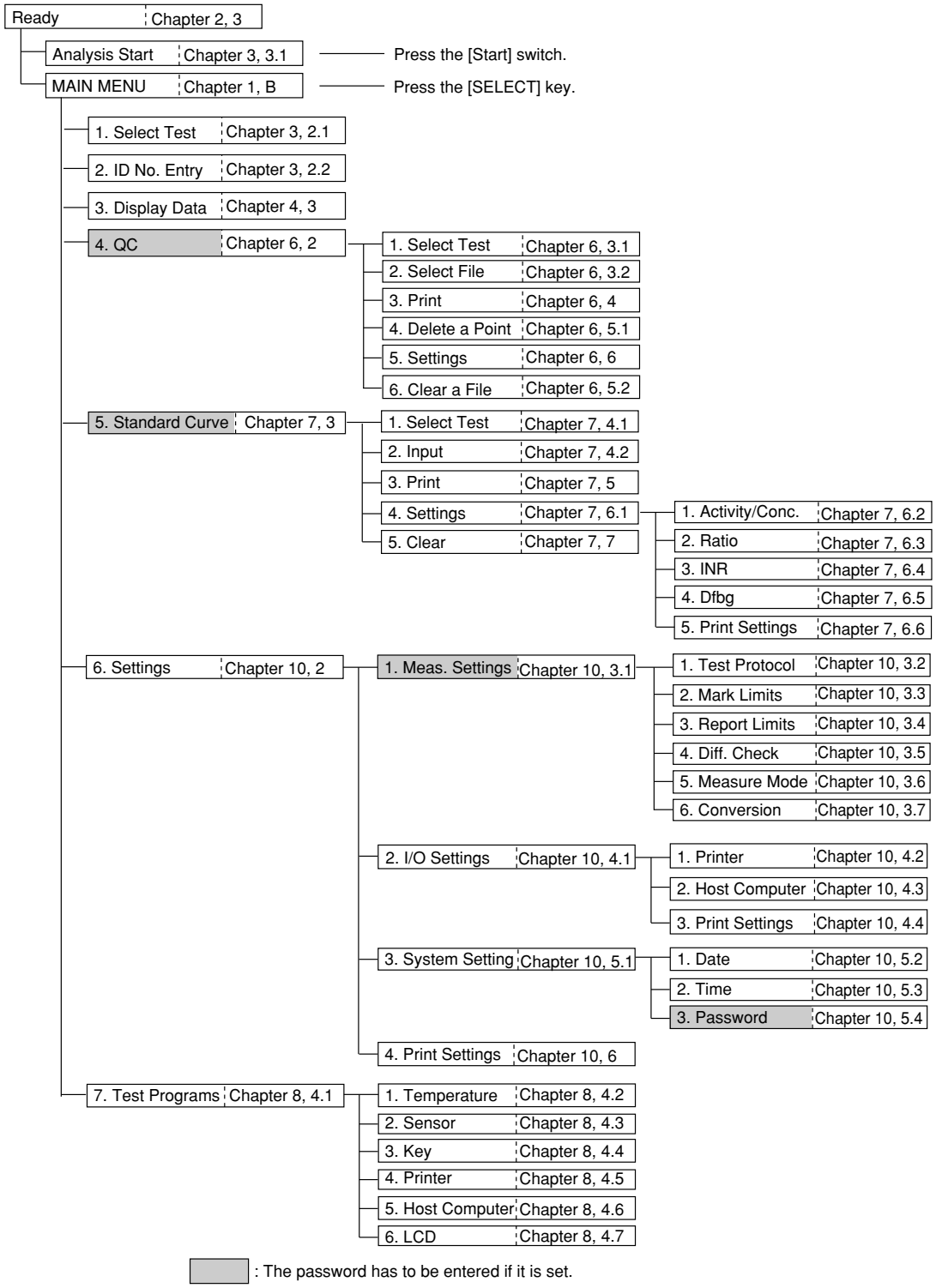
CAUTION Interpretation of APTT Abnormal Early Reaction.

- APTT results less than or equal to 20.0 seconds, APTT results with NC (No Coagulation), SC (Slight Coagulation) or CCE (Coag. Curve Error) error messages, or abnormally short APTT results may be caused by an abnormal early reaction.
  APTT results with an abnormal early reaction can be identified in the analysis data.
- If an APTT result less than or equal to 20.0 seconds is obtained, the following steps should be taken:

  1. Verify sample and reagent integrity along with maintenance procedures.
  2. Print out the Analysis data.
     See *Chapter 4, Section 4: OUTPUTTING ANALYSIS RESULT and Chapter 10, Section 4.2: Built-In Printer Settings.*
     Note that the stored analysis results will be deleted, when you start a next analysis on the same channel or you turn OFF the power or so on.
  3. Observe time in the “2%” position.
  4. If that time is equal to or less than 15 seconds, then an abnormal early reaction may have occurred.
  5. Re-analyze the sample.
  6. If result is the same, it should not be reported.
  7. Review the previous patient history to determine acceptability of patient results. Results of the other parameters considered, then make overall evaluation.
  8. Follow your laboratory's alternate protocol.

- An error code may or may not be associated with this result.
- An abnormal early reaction rarely occurs.
- The CA-50 should be set up so that any APTT results of less than or equal to 20.0 seconds will have a message of <20.1 seconds on the print-out.
- To set up this function *see Chapter 10, Section 3.4: Report Limit Settings* and enter 20.1 for the APTT lower limit.
- Remember to change the Built-in Printer Settings back to “List” after review of the analysis data.

12. MENU TREE


Ready Chapter 2, 3
Analysis Start Chapter 3, 3.1
Press the [Start] switch.
MAIN MENU Chapter 1, B
Press the [SELECT] key.
1. Select Test Chapter 3, 2.1
2. ID No. Entry Chapter 3, 2.2
3. Display Data Chapter 4, 3
4. QC Chapter 6, 2
1. Select Test Chapter 6, 3.1
2. Select File Chapter 6, 3.2
3. Print Chapter 6, 4
4. Delete a Point Chapter 6, 5.1
5. Settings Chapter 6, 6
6. Clear a File Chapter 6, 5.2
5. Standard Curve Chapter 7, 3
1. Select Test Chapter 7, 4.1
2. Input Chapter 7, 4.2
3. Print Chapter 7, 5
4. Settings Chapter 7, 6.1
1. Activity/Conc. Chapter 7, 6.2
2. Ratio Chapter 7, 6.3
3. INR Chapter 7, 6.4
4. Dfbg Chapter 7, 6.5
5. Print Settings Chapter 7, 6.6
5. Clear Chapter 7, 7
6. Settings Chapter 10, 2
1. Meas. Settings Chapter 10, 3.1
1. Test Protocol Chapter 10, 3.2
2. Mark Limits Chapter 10, 3.3
3. Report Limits Chapter 10, 3.4
4. Diff. Check Chapter 10, 3.5
5. Measure Mode Chapter 10, 3.6
6. Conversion Chapter 10, 3.7
2. I/O Settings Chapter 10, 4.1
1. Printer Chapter 10, 4.2
2. Host Computer Chapter 10, 4.3
3. Print Settings Chapter 10, 4.4
3. System Setting Chapter 10, 5.1
1. Date Chapter 10, 5.2
2. Time Chapter 10, 5.3
3. Password Chapter 10, 5.4
4. Print Settings Chapter 10, 6
7. Test Programs Chapter 8, 4.1
1. Temperature Chapter 8, 4.2
2. Sensor Chapter 8, 4.3
3. Key Chapter 8, 4.4
4. Printer Chapter 8, 4.5
5. Host Computer Chapter 8, 4.6
6. LCD Chapter 8, 4.7
: The password has to be entered if it is set.

13. MAIN MENU

The Main Menu screen shows the menu for selecting and utilizing the functions provided with the CA-50.

When you press the [SELECT] key on the Ready screen, the Main Menu screen will appear. For details on the Ready screen, see *Chapter 2, Section 3: TURNING ON THE POWER*.
You can scroll the menu up and down by using the [Λ] and [V] keys.

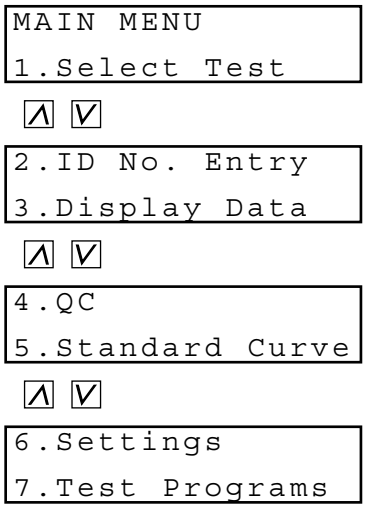


Figure 1-7: Main Menu Screen

Pressing the following key will select each menu function.

[1] key:	Moves the screen to the selection of analysis parameters (Select Test).
[2] key:	Moves the screen to the entry of ID numbers (ID No. Entry).
[3] key:	Moves the screen to the display of detailed analysis results (Display Data).
[4] key:	Displays the quality control menu (QC).
[5] key:	Displays the standard curve menu (Standard Curve).
[6] key:	Displays the setting menu (Settings).
[7] key:	Displays the test program menu (Test Programs).
[PRINT] key:	Prints out the main menu.
[SELECT] key:	Returns the screen to the Ready screen.

CHAPTER 2 ANALYSIS PREPARATION

1. INTRODUCTION ……2-1

2. BEFORE TURNING ON THE POWER ……2-2

3. TURNING ON THE POWER ……2-2

4. REAGENT PREPARATION……2-4
   4.1 Preparing the Reagents ……2-4
   4.2 Setting the Reaction Tubes and Reagents……2-5

5. CHECKING THE STANDARD CURVES ……2-6

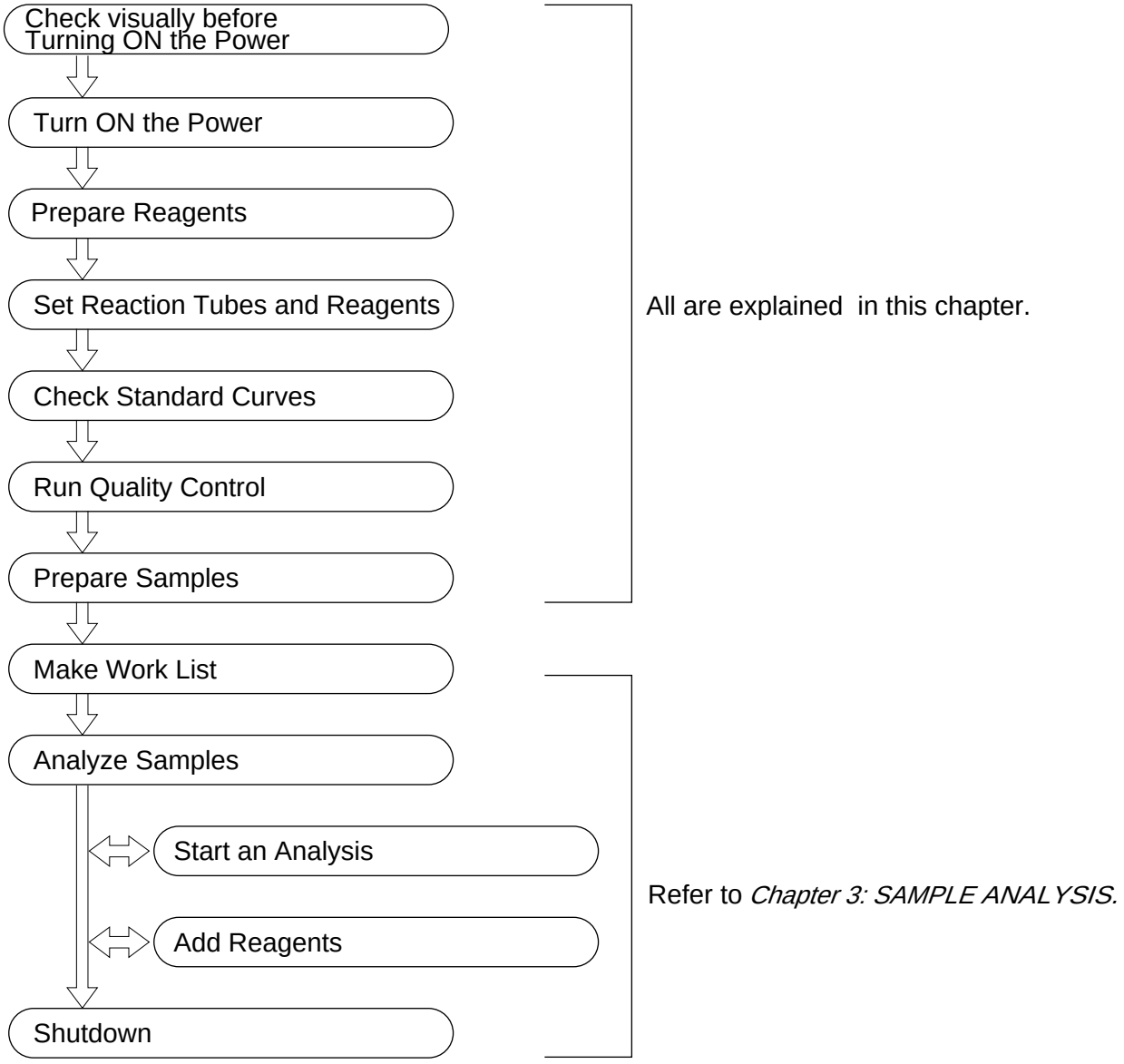
6. QUALITY CONTROL ……2-7

7. SAMPLE PREPARATION ……2-8

1. INTRODUCTION

Before beginning analysis, it is necessary to prepare the instrument, reagents, and samples. Prepare for analysis by following the steps described below.

Table 2-1: Analysis Flow Chart



2. BEFORE TURNING ON THE POWER

Before turning ON the power to the instrument, check the following items:

1. CA-50 Instrument Visual Check
Make sure that the power cord is securely plugged into the AC outlet.
Also, check whether the used reaction tube is not left in the detector.

2. Printer Paper
If a printer is provided, make sure that it contains the amount of paper necessary for the number of samples to be processed that day. Prepare extra paper when the remains of paper run short.

3. TURNING ON THE POWER

When you turn ON the power switch that is located on the right side, the instrument will automatically perform a self-check.

(1) Turn ON the power switch.
A self-check will automatically be performed. When the self-check is completed without finding any error, "OK" will be displayed on the screen and the built-in printer will output a test print.
If an error occurs during the self-check, see *Chapter 8: TROUBLESHOOTING.*

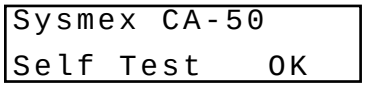


Figure 2-1: Self-Check Screen

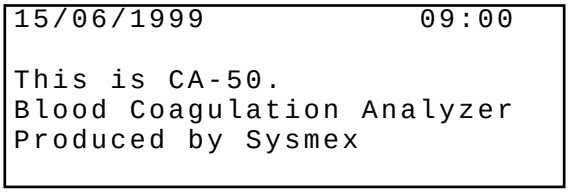


Figure 2-2: Example of Test Print

When the self-check is completed, the detector and the incubator will be warmed up. During the warming-up, "warm" will be displayed on each channel of the screen.

NOTE: • The analysis parameter that was used in the previous analysis is displayed on each channel.

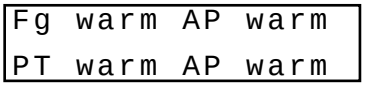


Figure 2-3: Warming-Up Screen

The "warm" will disappear and the detector LED will light up in green one by one as soon as each channel completes the warming-up. It takes about 5 minutes to 30 minutes until the "warm" disappears.
This status is called "Ready." You can perform various operations such as analysis and settings on the channel that has entered the "Ready" status.

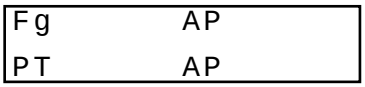


Figure 2-4: Ready Screen

If you press the [SELECT] key on this screen, the Main Menu screen will appear. For details on the Main Menu screen, see *Chapter 1, Section 13: MAIN MENU*.

4. REAGENT PREPARATION

4.1 Preparing the Reagents

Prepare the required volume of coagulation reagents and Owren's Veronal buffer for the anticipated work load.

Table 2-2: Reagent Preparation

Parameter	Reagent	Consumption/Test
PT	PT Reagent	100 µL
APTT	APTT Reagent	50 µL
	Calcium Chloride Solution	50 µL
Fbg	Thrombin Reagent	50 µL
	Owren's Veronal Buffer	90 µL
TTO	Thrombotest Reagent	125 µL
	Owren's Veronal Buffer	30 µL
NT	Normotest Reagent	125 µL
	Owren's Veronal Buffer	40 µL
TT	Thrombin Time Reagent	50 µL
Extrinsic Factor Deficient Assay	PT Reagent	100 µL
	Factor-deficient Plasma	50 µL
	Owren's Veronal Buffer	45 µL
Intrinsic Factor Deficient Assay	APTT Reagent	50 µL
	Calcium Chloride Solution	50 µL
	Factor-deficient Plasma	50 µL
	Owren's Veronal Buffer	45 µL

When you prepare reagents, take into account the analysis parameters and the number of samples to be analyzed.

CAUTION:
- We recommend that you use the following pipettes and pipette chips to add plasma and dispense/add reagents.
  - Pipette: Eppendorf reference 4910 (50 - 200 µL)
  - Pipette chip: Eppendorf 300 µL chip

  For details on the usage of the pipette and pipette chip, refer to the instruction manuals attached to them.

4.2 Setting the Reaction Tubes and Reagents

Set reaction tubes and reagents into the instrument.

(1) Set reaction tubes into the reaction tube holder. Prepare a sufficient number of reaction tubes beforehand.

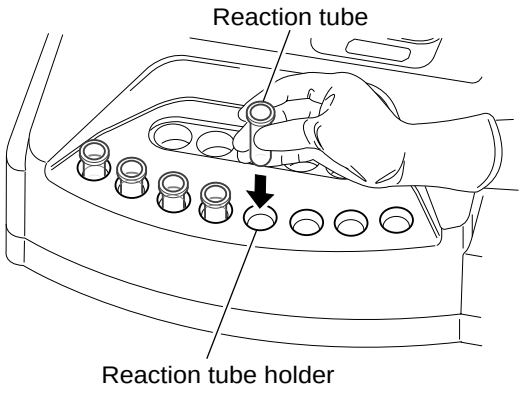


Figure 2-5: Setting the Reaction Tubes

CAUTION:	• Be sure to use the specified reaction tube (SU-40).

(2) Dispense the reagents to be used into the sample cups, and set them into the incubator.

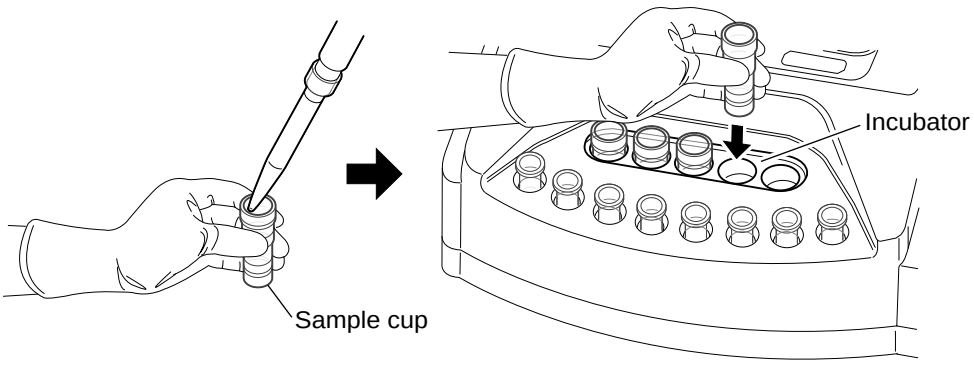


Figure 2-6: Setting the Reagents

WARNING

- Cap the sample cups that are set in the incubator if they are not used. If contaminants or dusts get in the reagent, or if the reagent evaporates, correct analysis results will not be obtained.
- Let the incubator incubate the reagents more than 10 minutes. If the incubation is insufficient, correct analysis results may not be obtained. As the reagent may deteriorate, do not use the APTT reagent incubated for 20 minutes or more and the other reagents incubated for 40 minutes or more.
- Do not replenish reagents. Correct analysis results may not be obtained.

CAUTION:

- Do not set the reagent of 2 mL or more in the incubator. The reagent will not reach the desired temperature.
- Be sure to use the specified sample cup (Uniflex Conical 4 mL or the equivalent).

5. CHECKING THE STANDARD CURVES

Before performing an analysis, print out standard curves and make sure that they are correctly set.
For the procedure to print out standard curves, see *Chapter 7, Section 5: PRINTING OUT THE STANDARD CURVE*.

CAUTION:

- If the standard curve is not set correctly, it is not possible to calculate the calculation parameters such as the PT %.

If the settings are incorrect, set them correctly referring to *Chapter 7: SETTING STANDARD CURVES*.

6. QUALITY CONTROL

To maintain reliable analysis data, it is necessary to implement quality control. With the CA-50, a quality control file number (QC1 - QC3) can be registered as a sample ID number, the control material (control plasma) is analyzed, and the analysis data is stored in a quality control file. This data and a quality control program are used to monitor changes in the instrument and reagent system that take place over time (day-to-day or hour-to-hour).

For details on quality control, see *Chapter 6: QUALITY CONTROL*.

Implementing Quality Control
When performing a quality control analysis, dispense control material into a reaction tube. The procedure for a quality control analysis is the same as that for a sample analysis. For details, see *Chapter 3: SAMPLE ANALYSIS*.

(1) Register the analysis parameter in the channel used for the analysis.

(2) Press the [QC] key on the ID No. Entry screen, and input the ID number for quality control (any number from 1 to 3).

(3) Dispense control material into a reaction tube and set it into the detector.

(4) Press the [Start] switch.

(5) Add a reagent at the indicated timing, and close the pipette guide.
The analysis will be performed, and the analysis data will be stored in a quality control file.

(6) Print out a QC chart and check the status of analysis data.

7. SAMPLE PREPARATION

Prepare sample tubes containing plasma.

NOTE:
- When handling the sample, be sure to wear rubber gloves. After the operation is completed, wash your hands with disinfectant solution. Failure to do so can cause infection by bacteria.

(1) Add 1 part of 3.8%, 3.2% or 3.13% sodium citrate solution as anticoagulant to 9 parts of venous blood, and mix the contents thoroughly.

(2) Centrifuge the mixture at 3000 rpm for 15 minutes to separate plasma components from blood-cell components.

(3) Put only the centrifuged plasma into another test tube.

CAUTION Precautions when handling plasma:
- Containers should be plastic or silicone-coated glass tube.
- As anticoagulant, use 3.8%, 3.2% or 3.13% sodium citrate solution. When any other anticoagulant is used, sedimentation may occur and correct analysis result may not be obtained.
- Mix blood and sodium citrate solution in an accurate ratio of 9 parts to 1 part, respectively. When the mixing ratio varies, coagulation time varies, occasionally leading to incorrect analysis result.
- Store samples in the refrigerator and analyze within 4 hours of collecting. After 4 hours, or if they are stored improperly, correct analysis results may not be obtained.

CHAPTER 3 SAMPLE ANALYSIS

1. INTRODUCTION 3-1

2. WORK LIST 3-2
   2.1 Selecting the Analysis Parameter 3-2
   2.2 Registering the Sample ID Number 3-4

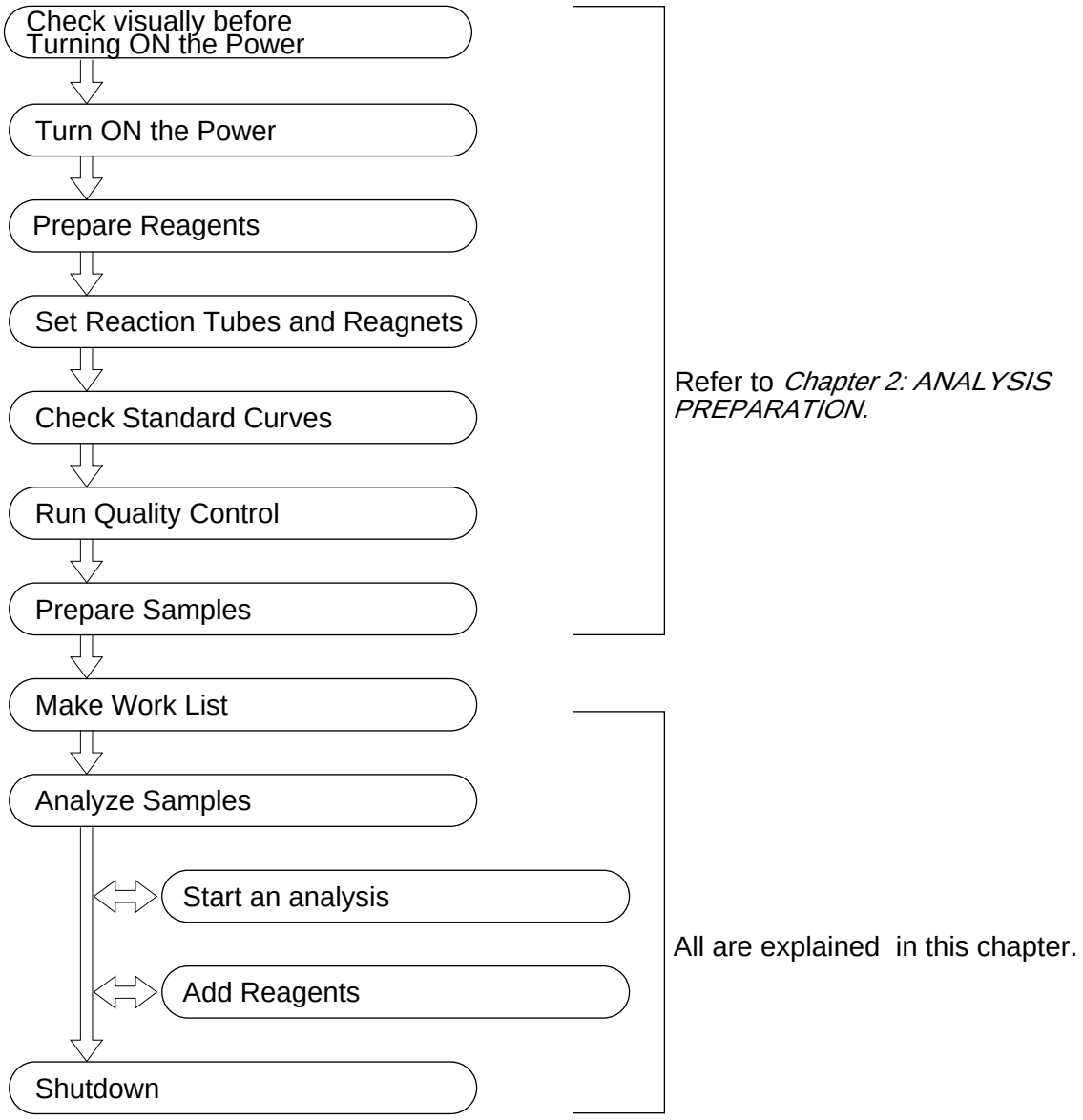
3. SAMPLE ANALYSIS 3-6
   3.1 Start of Analysis 3-7
   3.2 Adding the Reagents 3-8
   3.3 Registering and Analyzing the Next Sample 3-11

4. SHUTDOWN 3-12

1. INTRODUCTION

This chapter will explain the operating procedures for the order information registration and from the start of analysis to shutdown.

Table 3-1: Analysis Flow Chart



2. WORK LIST

Register the analysis parameter and the sample ID number of each channel.

2.1 Selecting the Analysis Parameter

NOTE: • When the power is turned ON, the analysis parameter used in the previous analysis is displayed on each channel.

(1) Press the [SELECT] key to enter the Main Menu screen.

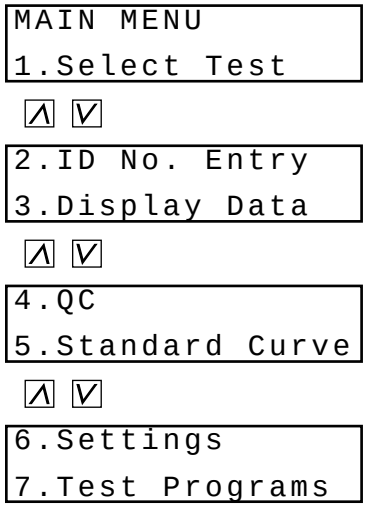


Figure 3-1: Main Menu Screen

(2) Press the [1] key on the Main Menu screen.
The Channel Selection screen will appear.

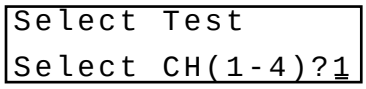


Figure 3-2: Channel Selection Screen

If you press the [SELECT] key, the display will return to the Main Menu screen (Figure 3-1).

(3) Input the channel number (any number from 1 to 4) on which you wish to select the analysis parameter, and press the [ENTER] key. However, when the replication measure mode is set (See *Chapter 10, Section 3.6: Measure Mode & Sample Incubation Ready Check Settings*.), select the channel number either 1 or 3.
The Analysis Parameter Selection screen will appear. (The parameter set in the previous analysis is displayed.)

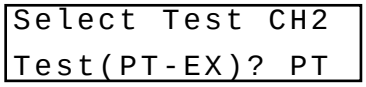


Figure 3-3: Analysis Parameter Selection Screen

If you press the [SELECT] key, the display will return to the Channel Selection screen (Figure 3-2).

(4) Press the key for the desired parameter, and press the [ENTER] key.
In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key.
In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key.
When you press the [IN] or [EX] key, the Factor Number Entry screen will appear.
When you press any of the other keys, the display will return to the Channel Selection screen (Figure 3-2). Set the analysis parameter of the other channels in the same manner.

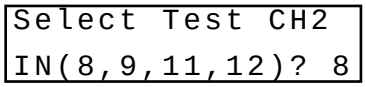


Figure 3-4: Factor Number Entry Screen

If you press the [SELECT] key, the display will return to the Channel Selection screen (Figure 3-2).

(5) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12.
In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10.
Then press the [ENTER] key.
The display will return to the Channel Selection screen (Figure 3-2). Set the analysis parameter of the other channels in the same manner.

2.2 Registering the Sample ID Number

(1) Press the [SELECT] key to enter the Main Menu screen.

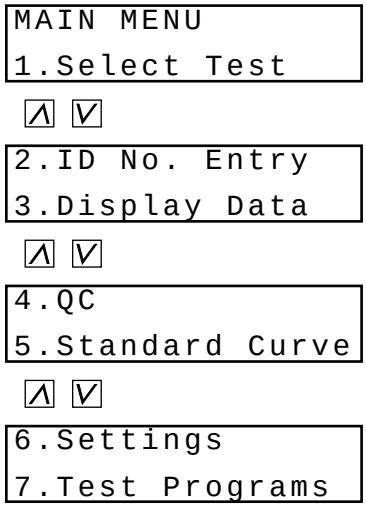


Figure 3-5: Main Menu Screen

(2) Press the [2] key on the Main Menu screen.
The Channel Selection screen will appear.

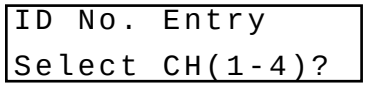


Figure 3-6: Channel Selection Screen

If you press the [SELECT] key, the display will return to the Main Menu screen (Figure 3-5).

(3) Input the channel number (any number from 1 to 4) on which you wish to register the sample ID number, and press the [ENTER] key.
The ID No. Entry screen will appear.

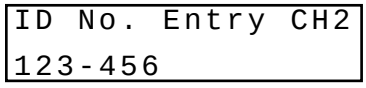


Figure 3-7: ID No. Entry Screen

If you press the [SELECT] key, the display will return to the Channel Selection screen (Figure 3-6).

(4) Input the ID number, and press the [ENTER] key.
The display will return to the Channel Selection screen (Figure 3-6). The sample ID number can be registered with up to 15 digits consisting of numerals and hyphens (-). The hyphens, however, cannot be used consecutively or as the first or last digits of the sample ID number.
When a quality control analysis is performed, press the [QC] key and input any number from 1 to 3.

NOTE:

- If you do not input a sample ID number after the power is turned ON, the number will be sequentially incremented from "1" in each analysis regardless of the channel or the analysis parameter.
- If a sample ID number is input, the number will be sequentially incremented from the ID number input last regardless of the channel or the analysis parameter.
- When a hyphen is used in the sample ID number, the subject of the automatic increment will be the digits after the hyphen.
  For example, when the sample ID number is "990601-99", the next number will be "990601-00."
- If "0" is input to the ID number, an external output will not be carried out. And, if "0", "QC1", "QC2", or "QC3" is input, the ID number will become only one time at the input without automatic incrementing.

3. SAMPLE ANALYSIS

When the detector LED is lit in green, you can perform an analysis on this channel. It is possible to perform analyses on multiple channels simultaneously.
The CA-50 has a function to turn off the detector LED indicating the Ready status and prevent an analysis from being started when the timings of reagent addition are expected to overlap one another.

WARNING

- Be sure to wear rubber gloves during the analysis. After the operation is completed, wash your hands with disinfectant solution. Failure to do so can cause infection by bacteria.
- Handle reaction tubes containing sample with extreme care in order to avoid any infection by bacteria.
  When discarding used reaction tubes, take proper disposing steps as medical and infectious wastes.
- The total volume of blood and reagents must be in the range of 150 to 200 μL. If the volume exceeds this range, sample may spill out of the reaction tube when being mixed, resulting in infection by bacteria.

CAUTION

- Be careful not to spill blood or reagents into the detector. This may damage the instrument.
- Use the correct volume of blood and reagents. If the volume is improper, correct analysis results may not be obtained, or addition of reagents may not be detected. For the specific volume required for each analysis, see *Chapter 9, Section 2.6: Analysis Flow*.
- Use a new pipette chip each time. Replace the pipette chip with a new one even when you add the same reagent consecutively. If sample is contaminated with the other sample or reagent, correct analysis results will not be obtained.
- Be careful so that reagents or contaminants will not get in the reaction tube. Correct analysis results will not be obtained.

3.1 Start of Analysis

(1) Pipette plasma into a reaction tube and set it into the detector.
At this time, push it into the bottom of the detector firmly.

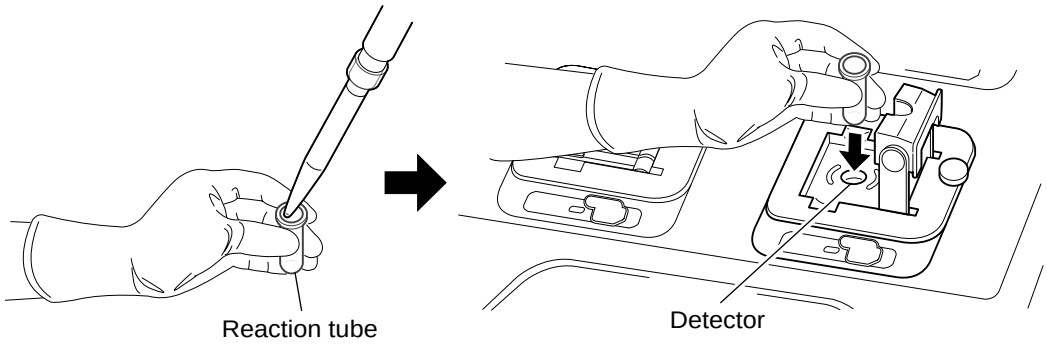


Figure 3-8: Setting Plasma

(2) Press the [Start] switch.
Incubation of plasma will start. The reagent to be added and the countdown of the remaining time before the reagent addition timing will be displayed on the screen. The detector LED will blink in red.

```
PT        Fg
AP        PT  179
```

Figure 3-9: Display of Countdown

CAUTION: • When you press the [Start] switch by mistake, you can cancel the analysis by pressing the [Start] switch again. However, the alarm sounds in this case, and stops the alarm by pressing the [C] key.

3.2 Adding the Reagents

When a reagent addition timing comes, an alarm will begin to sound and the detector LED will blink in green. The detailed operations of the alarm and the detector LED are as shown below:

Table 3-2: Reagent Addition Timing Alarm

Reagent addition allowed time (start)		5 seconds before	• • •	Reagent addition	• • •	Reagent addition allowed time (end)
Two short beeps	No sound	A short beep	A short beep	A long beep	A short beep	A long beep
			One beep per second	For 0.5 seconds	One beep per second	An error beep

Allowed time for reagent addition

The time allowed for reagent addition is preset at 10 seconds as default; 5 seconds before and after the time of addition. If you wish to change the allowed time, see *Chapter 10, Section 3.2: Test Protocol Settings.*

Table 3-3: Operation of Detector LED

During warming-up	Ready	During incubation	Reagent addition timing	During photo detection	Ready
Turns off	Lights up in green	Blinks in red	Blinks in green	Lights up in red	Lights up in green

(1) When the alarm begins to sound, take the reagent to be added with a pipette.

CAUTION
- When two or more reagents are set in the incubator, be careful not to mix up them. If an incorrect reagent is used, correct analysis results will not be obtained.
- Use the reagent incubated more than 10 minutes. If the incubation is insufficient, correct analysis results may not be obtained.
  Also, as the reagent may deteriorate, do not use the APTT reagent incubated for 20 minutes or more and the other reagents incubated for 40 minutes or more.
- Do not replenish reagents. Correct analysis results may not be obtained.

CAUTION:
- We recommend that you use the following pipettes and pipette chips to pipette plasma and dispense/add reagents.
  - Pipette: Eppendorf reference 4910 (50 - 200 μL)
  - Pipette chip: Eppendorf 300 μL chip

  For details on the usage of the pipette and pipette chip, refer to the instruction manuals attached to them.
- Use the pipette correctly calibrated.

(2) Add the reagent when a long beep sounds.
Add the reagent in a manner as to avoid bubbling the sample, while fixing the pipette chip to the pipette guide and **applying the tip of the pipette chip to the inside wall of the reaction tube.**

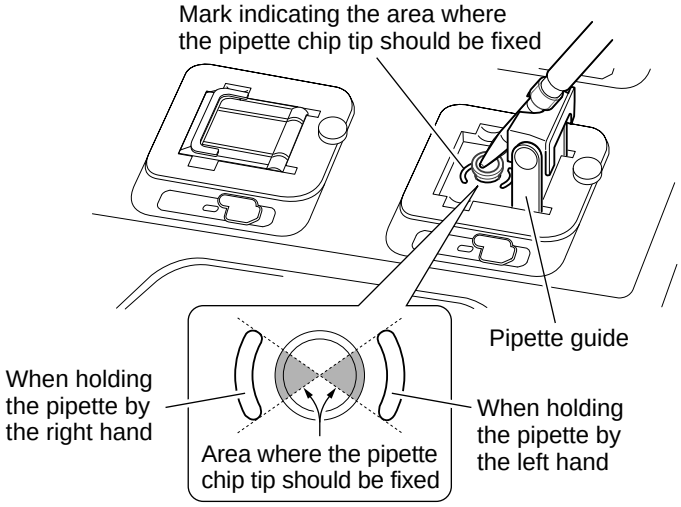
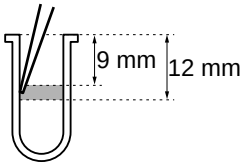

Mark indicating the area where the pipette chip tip should be fixed
Pipette guide
When holding the pipette by the right hand
When holding the pipette by the left hand
Area where the pipette chip tip should be fixed

Figure 3-10: Adding the Reagent

CAUTION
- When you use multiple channels simultaneously, be careful not to mix up the detectors. If you add a reagent into an incorrect detector, correct analysis results will not be obtained.

CAUTION:

- Add the reagent to the reaction tube quickly after pipetting. However, handle the pipette gently when dispensing and slowly when pipetting.
- Add the reagent within the time allowed for the addition. If the reagent addition is not performed within the allowed time, an analysis error will occur.
- The pipette guide is designed for the use of the recommended pipette chip. If you use the other type of pipette chip, you may not be able to fix it properly and reagent addition may not be detected.
- When you add reagents, the tip of the pipette chip must be fixed in the area shown in Figure 3-10. If the tip is out of this area, reagent addition may not be detected.
- When you add reagents, the tip of the pipette chip must be in the area shown in the figure below. If the tip is out of this area, reagent addition may not be detected properly, and the sensor may detect the tip of the pipette chip as the reagent by mistake.



- Do not add less than 50 μL of reagent. Reagent addition may not be detected properly.
- Do not add reagent when the volume of sample and reagent is 200 μL or more. Reagent addition may not be detected properly.

NOTE:

- You can prevent sample from bubbling by applying the tip of the pipette chip to the inside wall of the reaction tube.

When a reagent is added, mixing will start automatically, and the detector LED will light up in red.
If the second reagent is required, the detector LED will blink in red and the countdown of the remaining time will appear again. Then go back to step (1) and add the reagent in the same manner.
If the second reagent is not required, go to the next step.

(3) Close the pipette guide as soon as you add the reagent.
Photo detection will start. ">" will be displayed on the screen as the detection progresses.

PT	Fg
AP	PT >>>

Figure 3-11: Display during Photo Detection

CAUTION:
- The pipette guide also serves as a lid to prevent disturbance light around the detector. If the stand is not closed within two seconds after the addition of reagent, an analysis error will occur.
  However, when you analyze the parameter for which the continuous addition of the reagent is necessary, it does not become an analysis error except at the last reagent addition.
- Do not open the pipette guide during photo detection. An analysis error will occur.

When the analysis is completed, the analysis parameter and analysis results will be displayed on the screen, and the detector LED will light up in green. For details on the data display, see *Chapter 4: DISPLAY OF ANALYSIS RESULTS.*
The analysis results can be outputted to the built-in printer or the host computer. For details on the settings of output, see *Chapter 10, Section 4: I/O SETTINGS.*

(4) Discard the used reaction tube.

WARNING
- Be sure to wear rubber gloves during the analysis. After the operation is completed, wash your hands with disinfectant solution. Failure to do so can cause infection by bacteria.
- Handle reaction tubes containing sample with extreme care in order to avoid any infection by bacteria.
  When discarding used reaction tubes, take proper disposing steps as medical and infectious wastes.

CAUTION:
- Close the pipette guide immediately after removing the used reaction tube. This will prevent the foreign object etc. being entered into the detector. Also, if the pipette guide is opened over 15 minutes, an error “Lid Open CH #” will occur.

3.3 Registering and Analyzing the Next Sample

When the analysis is completed at a certain channel, you can register the next sample and start an analysis even if the other channels are still in process. However, when the replication measure mode is selected, the registration and analysis of the next sample cannot be performed until both channels used in a pair complete the analysis.

4. SHUTDOWN

Check the status of the instrument, and then turn the power OFF.

CAUTION: • At the end of each day's operations or after operating the instrument for 24 hours, perform daily maintenance. For details, see *Chapter 5: MAINTENANCE & SUPPLIES REPLACEMENT.*

CHAPTER 4 DISPLAY OF ANALYSIS RESULT

1. INTRODUCTION..... 4-1

2. DISPLAYING AND PRINTING OUT ANALYSIS RESULTS..... 4-1
   2.1 Displaying the Analysis Results..... 4-1
   2.2 Printing Out the Analysis Results..... 4-3

3. DISPLAYING DETAILED ANALYSIS RESULTS..... 4-5

4. OUTPUTTING ANALYSIS RESULTS..... 4-7

1. INTRODUCTION

This chapter explains the method of displaying and outputting analysis results.

CAUTION:
- The CA-50 stores only the last analysis results of each channel. Note that the stored analysis results will be deleted in the following cases:
  - When you change the analysis parameter.
  - When you change the sample ID number.
  - When you change the measure mode.
  - When you start the next analysis on the same channel.
  - When you turn OFF the power.

2. DISPLAYING AND PRINTING OUT ANALYSIS RESULTS

When an analysis is completed, the analysis parameter and the analysis results will be displayed on the screen. They can be printed out by the built-in printer at the same time.

2.1 Displaying the Analysis Results

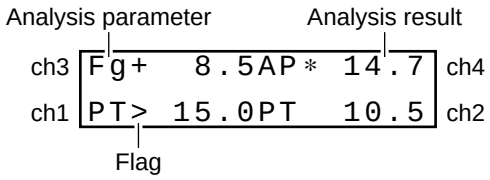


Figure 4-1: Analysis Results Screen

Analysis Parameter
The analysis parameter carried out on each channel is displayed.

Analysis Results
The analysis result of the preset data check parameter is displayed. For details on the data check parameter settings, see *Chapter 10, Section 3.3: Data Check Parameter & Mark Limit Settings.*

NOTE:
- When the replication measure mode is selected, the mean data of two channels' analysis results will be displayed. You can check the results of each channel on the Display Data screen (see *Chapter 4, Section 3: DISPLAYING DETAILED ANALYSIS RESULTS*.).

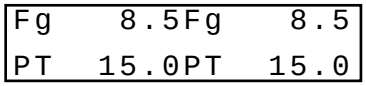


Figure 4-2: Analysis Results Screen in the Replication Measure Mode

Flag

When the analysis results are judged to be abnormal, one of the flags shown below will appear on the left of the analysis results.

*: An error occurred, or data disparity exists between replication analysis results. (Priority: high)
>: Data exceeded the upper report limit. (Priority: middle)
<: Data exceeded the lower report limit. (Priority: middle)
+: Data exceeded the upper mark limit. (Priority: low)
- : Data exceeded the lower mark limit. (Priority: low)
When two or more conditions are applicable, the flag of higher priority will be displayed.

The following figure shows the relation between the report limits and the mark limits. Note that this relation holds when the lower mark limit is smaller than the upper mark limit.
For mark limits, it is possible that you set a smaller value (e.g. shorter time) as the upper limit and a larger value (e.g. longer time) as the lower limit. In this case, "+" will appear when the analysis results are smaller than the upper limit, and "-" will appear when the analysis results exceed the lower limit.

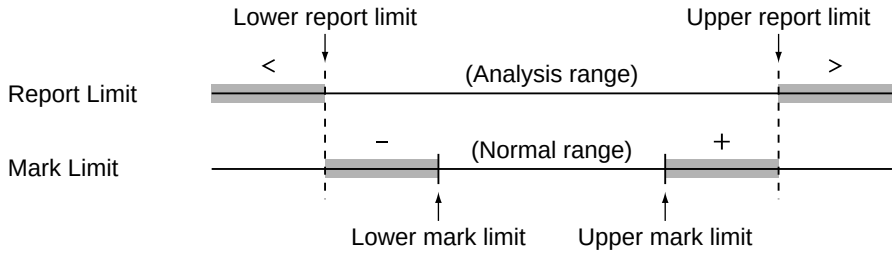


Figure 4-3: Relation between Report Limits and Mark Limits

2.2 Printing Out the Analysis Results

For printing out analysis results, there are three types of formats - list, graph, and analysis. For details on the setting of printout formats, see *Chapter 10, Section 4.2: Built-In Printer Settings.*

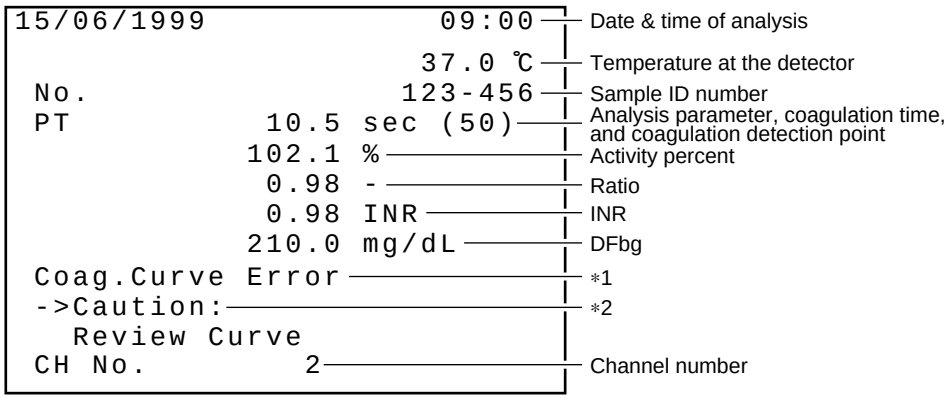


Figure 4-4: Printout Example (List)

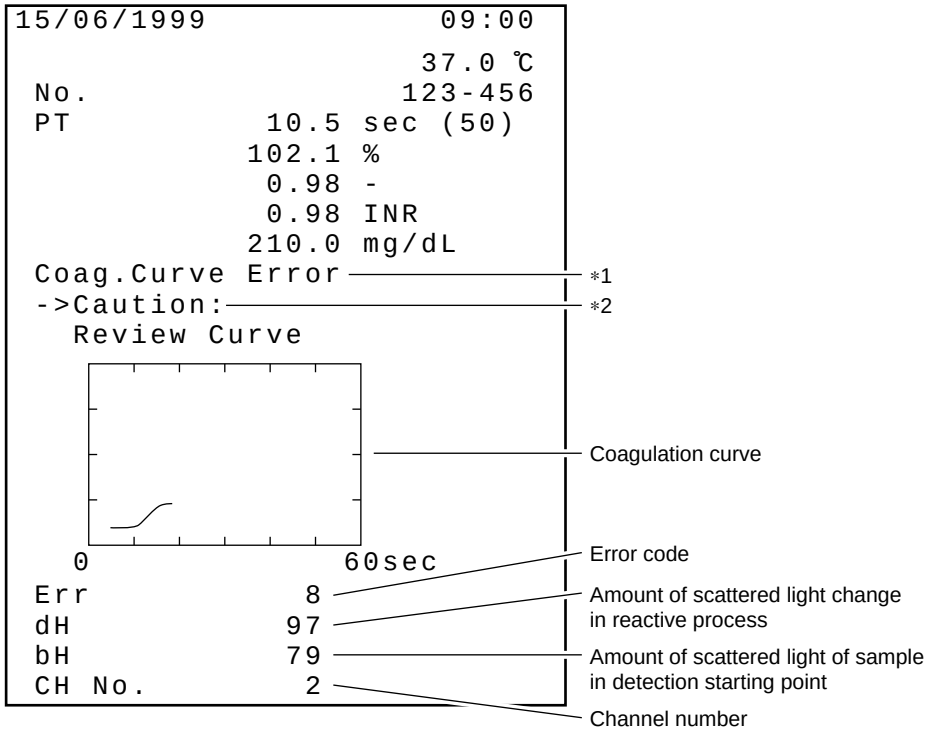


Figure 4-5: Printout Example (Graph)

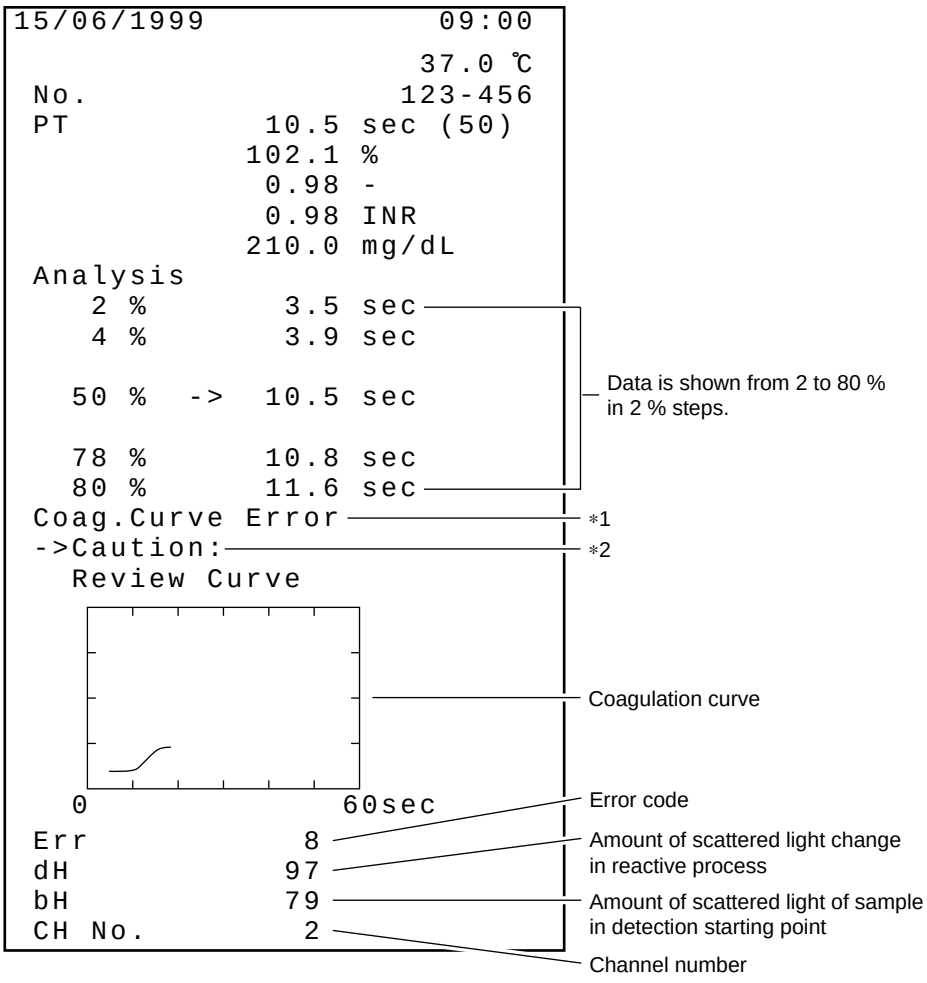


Figure 4-6: Printout Example (Analysis)

*1: When there are errors in the analysis results, all the errors will be printed with messages.
- For details on the errors, see *Chapter 8, Section 3.3: Analysis Data Errors and Corrective Actions.*

*2: This message will be printed when there is an abnormality in the coagulation curve.
- In the case of mean data, "MEAN CH1&2" or "MEAN CH3&4" will be printed under the date. There is no coagulation curve and analysis data for mean data.
- When the replication measure mode is selected, mean data and the data obtained on respective channels will be printed after the analysis is completed on two channels used in a pair.

3. DISPLAYING DETAILED ANALYSIS RESULTS

The Display Data screen displays detailed analysis results such as the results of all the calculation parameters selected.

(1) Press the [SELECT] key to enter the Main Menu screen.

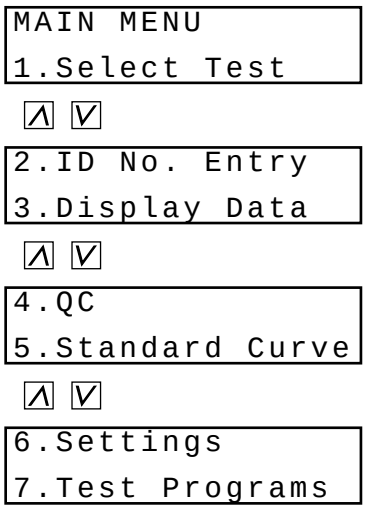


Figure 4-7: Main Menu Screen

(2) Press the [3] key on the Main Menu screen.
The Channel Selection screen will appear.

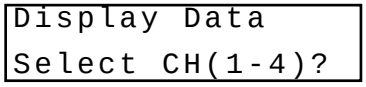


Figure 4-8: Channel Selection Screen

If you press the [SELECT] key, the display will return to the Main Menu screen (Figure 4-7).

(3) Input the channel number (any number from 1 to 4) on which you wish to display detailed analysis results, and press the [ENTER] key.
The Display Data screen will appear.
You can scroll the screen up and down by using the [Λ] and [V] keys.

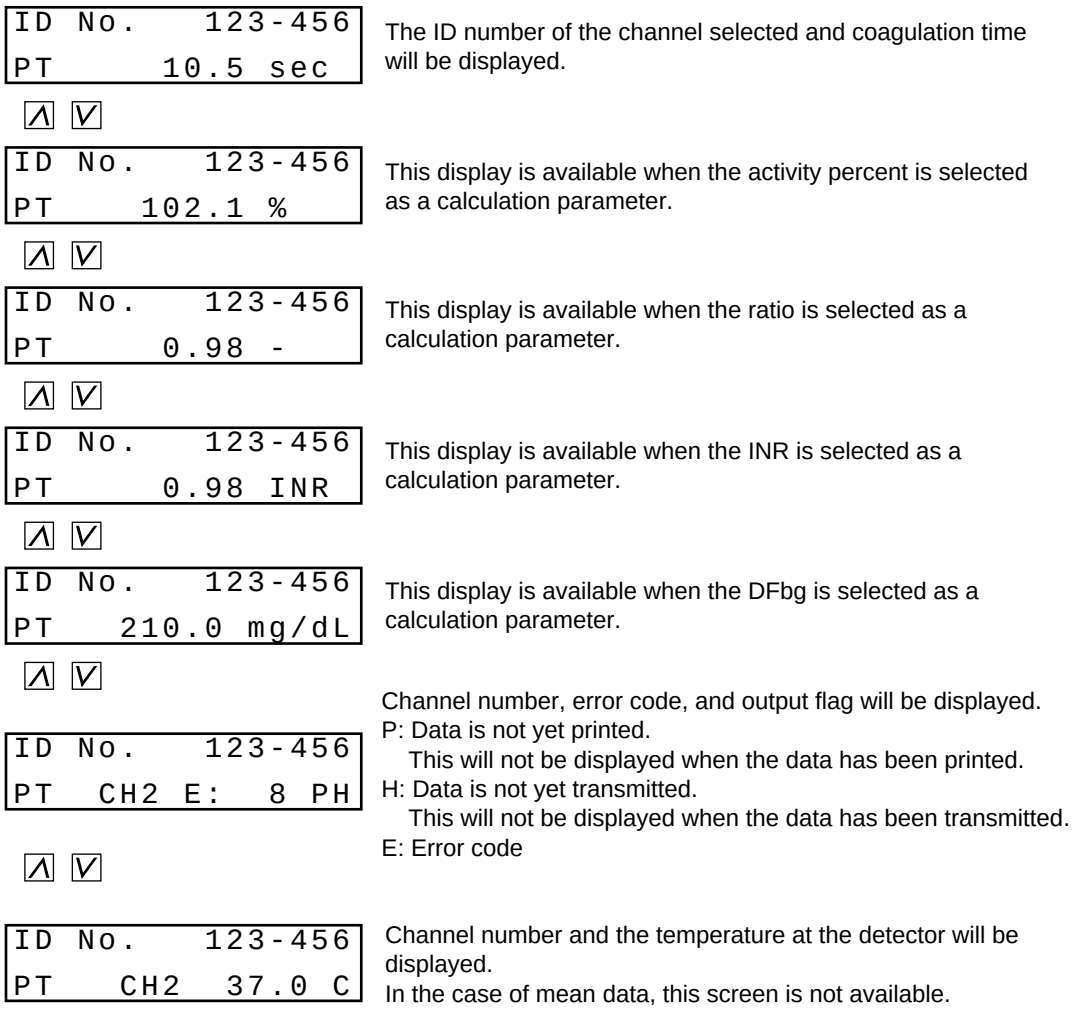

ID No. 123-456
PT 10.5 sec
Λ V
The ID number of the channel selected and coagulation time will be displayed.
ID No. 123-456
PT 102.1 %
Λ V
This display is available when the activity percent is selected as a calculation parameter.
ID No. 123-456
PT 0.98 -
Λ V
This display is available when the ratio is selected as a calculation parameter.
ID No. 123-456
PT 0.98 INR
Λ V
This display is available when the INR is selected as a calculation parameter.
ID No. 123-456
PT 210.0 mg/dL
Λ V
This display is available when the DFbg is selected as a calculation parameter.
ID No. 123-456
PT CH2 E: 8 PH
Λ V
Channel number, error code, and output flag will be displayed.
P: Data is not yet printed.
This will not be displayed when the data has been printed.
H: Data is not yet transmitted.
This will not be displayed when the data has been transmitted.
E: Error code
ID No. 123-456
PT CH2 37.0 C
Channel number and the temperature at the detector will be displayed.
In the case of mean data, this screen is not available.

Figure 4-9: Display Data Screen

- When the replication measure mode is selected, the screen will be scrolled in the order of mean data, channel 1 (or 3), and channel 2 (or 4) each time the [V] key is pressed. In this case, the same data will be displayed for both channel 1 (or 3) and channel 2 (or 4).
- When mean data is displayed, "m" will appear on the right of the analysis parameter. Also, the channel number in this case will be "1&2" or "3&4".
- If you press the [PRINT] key, the analysis results will be outputted to the designated device. For details on the settings of output, see *Chapter 10, Section 4: I/O SETTINGS.*
- If you press the [SELECT] key, the display will return to the Channel Selection screen (Figure 4-8).
- When the ID number consists of 11 digits or more, "ID No." will not be displayed. (Only the ID number will be displayed.)

4. OUTPUTTING ANALYSIS RESULTS

Output of analysis results will be performed automatically after the analysis is completed. If you wish to output the results again or when it was impossible to output them for some reason, you can output the data by the following procedure.

CAUTION:
- The CA-50 stores only the last analysis results of each channel. Note that the stored analysis results will be deleted in the following cases:
  - When you change the analysis parameter.
  - When you change the sample ID number.
  - When you change the measure mode.
  - When you start the next analysis on the same channel.
  - When you turn OFF the power.

(1) Press the [PRINT] key on the Display Data screen.
When it is set to output the analysis results to the host computer, the Output Device Selection screen will appear.
When this is not set, output to the built-in printer will start.

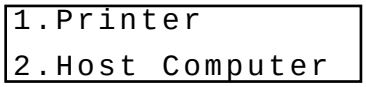


Figure 4-10: Output Device Selection Screen

If you press the [SELECT] key, the display will return to the Display Data screen (Figure 4-9).

(2) Select the desired output device.
If you wish to select the built-in printer, press the [1] key; if the host computer, press the [2] key.

If you press the [1] key, the following screen will appear and the built-in printer will start printing out the analysis results.

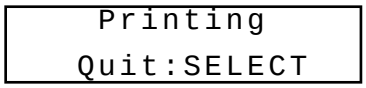


Figure 4-11: Printout Screen

- If you press the [SELECT] key, the printout will be canceled and the display will return to the Output Device Selection screen (Figure 4-10).
- For details on the printout format, see *Section 2.2: Printing Out the Analysis Results*.

If you press the [2] key, the following screen will appear and the analysis results will be transmitted to the host computer.

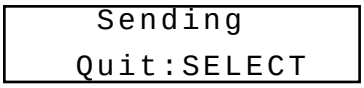


Figure 4-12: Transmission Screen

- If you press the [SELECT] key, the transmission will be canceled and the display will return to the Output Device Selection screen (Figure 4-10).
- For details on the settings of the host computer, see *Chapter 10, Section 4.3: Host Computer Settings and Appendix B.*

CHAPTER 5 MAINTENANCE & SUPPLIES REPLACEMENT

1. INTRODUCTION 5-1

2. CA-50 MAINTENANCE CHECKLIST 5-2

3. DAILY MAINTENANCE AND INSPECTION 5-3
   3.1 Cleaning the Reaction Tube Holder, Incubator, and Pipette guide 5-3

4. WEEKLY MAINTENANCE AND INSPECTION 5-4
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   5.3 Supply Parts List 5-8

1. INTRODUCTION

To ensure the instrument will serve you in the optimal operating condition, it requires periodic maintenance. Follow the maintenance schedule as described below and keep the result in the Maintenance Checklist.

- **Daily Maintenance**
  Clean the reaction tube holder
  Clean the incubator
  Clean the pipette guide

- **Weekly Maintenance**
  Clean the instrument
  Cleaning by blower

This chapter describes supplies replacement in addition to those inspection items mentioned above:

- **Supplies Replacement**
  Replace fuses
  Replace printer paper

2. CA-50 MAINTENANCE CHECKLIST

Month _____ Year _____

DAILY MAINTENANCE

Maintenance item \ Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean the reaction tube holder																															
Clean the incubator																															
Clean the pipette guide																															
Signature																															

WEEKLY MAINTENANCE/SUPPLIES REPLACEMENT

Maintenance item	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature
Clean the instrument						
Cleaning by blower						

AS-NEEDED MAINTENANCE/SUPPLIES REPLACEMENT

Maintenance item	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature
Replace the fuses						
Replace the printer paper						

3. DAILY MAINTENANCE AND INSPECTION

3.1 Cleaning the Reaction Tube Holder, Incubator, and Pipette guide

If samples and/or reagents are contaminated with foreign matters, correct analysis results will not be obtained. Wipe off the reaction tube holder, incubator, and pipette guide after the operation is completed.

⚠WARNING
- Before cleaning the reaction tube holder, incubator, and pipette guide, be sure to turn the power OFF and unplug the power cord. This is necessary to avoid the risk of electrical shock.
- Be sure to wear rubber gloves during the cleaning. After the cleaning is completed, wash your hands with disinfectant solution. If the instrument is contaminated with blood, infection by bacteria can occur.

(1) Turn OFF the power and unplug the power cord.

(2) Wipe off each part with a cloth that was moistened with water and wrung dry.
When dirt is hard to remove, wipe off the instrument with a cloth that was moistened with water and a neutral detergent, and then wipe again with a soft, dry piece of cloth.

CAUTION:
- Never use any other cleaning solution than water and a neutral detergent. Otherwise, the surface coating may be damaged.

4. WEEKLY MAINTENANCE AND INSPECTION

4.1 Cleaning the Instrument

To maintain the instrument in good condition, it should be cleaned once a week.

WARNING
- Before cleaning the instrument, be sure to turn the power OFF and unplug the power cord. This is necessary to avoid the risk of electrical shock.
- Be sure to wear rubber gloves during the cleaning. After the cleaning is completed, wash your hands with disinfectant solution. If the instrument is contaminated with blood, infection by bacteria can occur.

(1) Turn OFF the power and unplug the power cord.

(2) Wipe off the dirt of the instrument surface with a cloth that was moistened with water and a neutral detergent, and then wipe again with a soft, dry piece of cloth.

(3) Remove the filter on the bottom surface. Wash it with water and dry it. Reinstall the filter on the instrument.

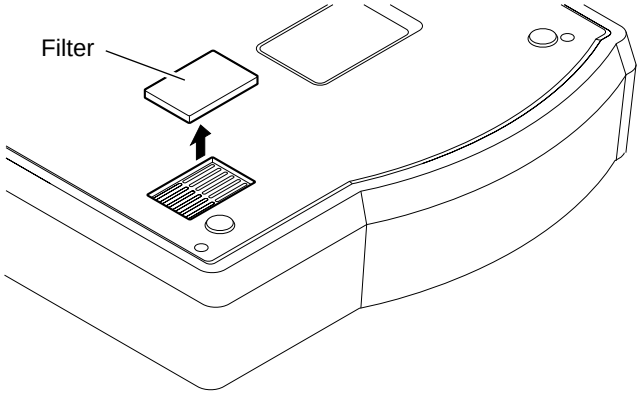

Figure 5-1: Cleaning the Filter

CAUTION:
- Never use any other cleaning solution than water and a neutral detergent. Otherwise, the surface coating may be damaged.

4.2 Cleaning by Blower

Clean the detector and the built-in printer every week by using a blower brush provided in the supply part.

(1) Turn OFF the power and unplug the power cord.

(2) Remove the reagents placed in the incubator.

(3) Detach the brush from the end of a blower brush.

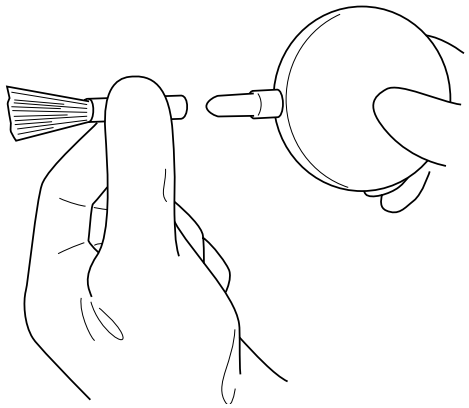

Figure 5-2: Detaching the brush

(4) Blow off dust on the surface of the instrument by using the blower with the pipette guide closed.

(5) Blow off dust of the outlet of the built-in printer.

(6) Open the pipette guide and remove the reaction tube in the detector.
Blow off dust of the inside the detector hole with the blower.
Blow the air approximately 20 times each channel. If a heavier dirt is expected, repeat blowing more.

Figure 5-3: Cleaning by blower

5. REPLACING SUPPLIES

5.1 Replacing Fuses

If a fuse is blown, replace it as described in the procedure below.

WARNING • To avoid risk of electrical shock, disconnect the power cord before replacing the fuses.

(1) Turn OFF the power and unplug the power cord.

(2) Using a regular screwdriver, pull out the two fuse holder caps on the rear face.

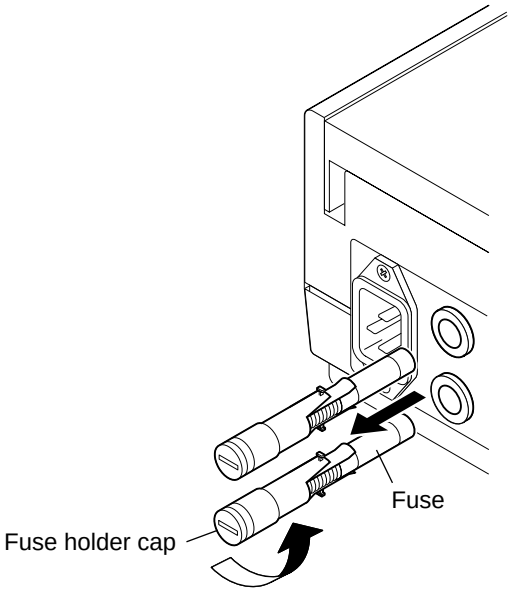

Figure 5-4: Replacing Fuses

(3) Replace the fuses and attach the fuse holder caps to the instrument.

CAUTION • For continued protection against risk of fire, replace only with a fuse of the specified type and current ratings.

Destination	Specification	Type	Quantity
117V	F1 250V 0.8A	Time Lag	2
220 - 240V	F1 250V 0.4A	Time Lag	2

5.2 Replacing Printer Paper

When the built-in printer has run out of paper, replace it in the procedure below.

(1) Open the built-in printer cover.

(2) Remove the remained print paper and the paper roll core.

CAUTION:
- When you intend to remove a remained portion of the printer paper, remove the roll core from the paper roll, press the [FEED] key, and then pull the paper.
  At this time, pull the paper out in the direction to which the printer paper is ejected at an ordinary print operation.
- Do not pull out the paper while printing.

(3) Set a new printer paper roll, and insert the end of paper to the built-in printer.

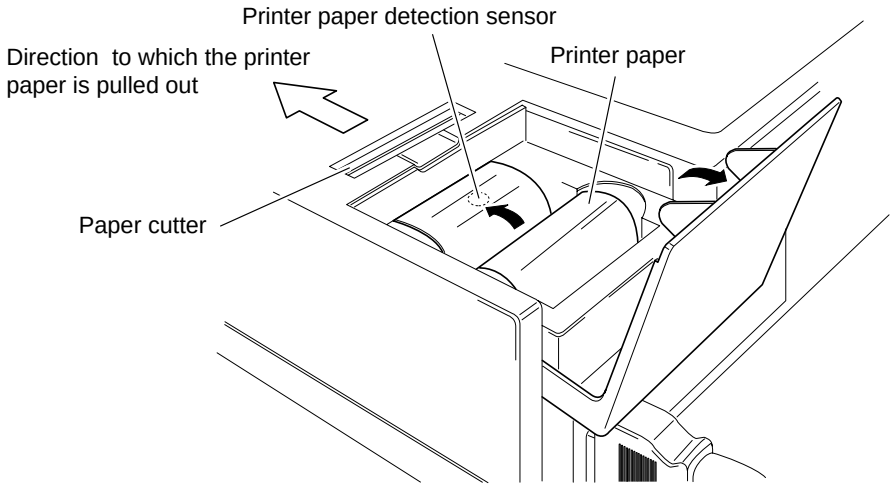

Figure 5-5: Setting a Printer Paper

CAUTION:
- Insert the printer paper straight to the built-in printer. Otherwise, the paper may be caught or the life of the printer head may be shorten.
- Use a specified printer paper. Otherwise, print cannot be performed, or the paper may be caught.
  Specification: F1-1
- As for the printing side of the paper, insert the printer paper as shown in Figure 5-3.
- Do not make the printer paper detection sensor dirty.
  The presence of printing paper might not be able to be detected correctly when becoming dirty. Wipe off dirt with a soft and dry cloth.
- Do not replace the printer paper by the wet hand.
  It causes paper jam.

(4) Press the [FEED] key until the top of the printer paper comes out of the outlet.

CAUTION:
- When paper jam occurs while printing, turn OFF the power of the Main Unit, and remove the paper cutter by sliding it to the instrument rear side, and then remove the printer paper.
  When you install the paper cutter, push it until the click sound is heard according to the reversed procedure of removal.

5.3 Supply Parts List

Part No.	Description	Remarks
904-0721-9	Reaction Tube SU-40	
424-1251-0	Sample Cup Conical 4 mL *1	
921-0352-1	Printer Paper F1-1	
266-5110-5	Fuse 250V 1A ST4-0.8A-N1 (N.Amer)	Main Unit, for 117V spec.
266-7132-4	Fuse S504 T0.4A-T	Main Unit, for 220V/240V specs.
369-5029-5	Indication Mark No. 1014 *2	
665-8038-1	Filter CA-5D	
421-9350-9	Blower Brush	

*1 For the Sample Cup, Uniflex Conical 4 mL or the equivalent can be used.
*2 Indication Mark No. 1014 is a label on which the analysis parameter is printed, and be affixed on the incubator and/or around the detector etc.

CHAPTER 6 QUALITY CONTROL

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1. INTRODUCTION

Quality control is implemented to ensure that highly reliable data is obtained over the long term and to constantly monitor the instrument condition to prevent inaccurate results from being reported.
The CA-50 analyzes control plasma and other samples (hereafter, quality control samples) and statistically manages the results.

1.1 Quality Control File

The CA-50 can maintain three quality control files (QC1 - QC3), with each file capable of saving up to 50 items of data. Up to 14 analysis parameters can be saved per file.

NOTE:
- To enable simultaneous quality control of both the current and new samples when quality control sample lots are switched, quality control files QC1 and QC2 are used for current control, and the remaining QC3 file is used to evaluate the new samples.

1.2 Quality Control Analysis

A quality control analysis is performed using quality control samples in the same procedures as that for an ordinary analysis. The quality control file number (QC1 to QC3) is registered as the sample ID number. When the analysis is completed, it is automatically saved in the quality control file instructed by the ID number. (See *Chapter 2, Section 6: QUALITY CONTROL*.)

The two quality control methods listed below are available.

$\overline{X}$ control: Analyzes QC samples with setting of the replication measure mode, and uses the average value as control data.

L-J control: Analyzes QC samples with setting of the single measure mode, and uses the data as control data. With L-J control, the range of control is easily affected by the reproducibility of analysis; thus, the range is wider than that of $\overline{X}$ control.

CAUTION:
- Use the quality control samples and reagents in accordance with the usage methods described in the package insert accompanied in each control material.
- Change to the measure mode used usually after executing the quality control.

Here, the example for the quality control analysis is explained.

(1) Prepare two kinds of the quality control samples (normality and abnormality).

(2) Assign the ID number for a normal sample to QC1, and analyze PT, APTT, and Fbg respectively.

(3) Assign the ID number for an abnormal sample to QC2, and analyze PT, APTT, and Fbg respectively.

(4) Select QC1 and PT respectively in the Quality Control Menu screen by referring to *Section 3: SELECTING THE QUALITY CONTROL FILE*.

(5) Perform *Section 4: PRINTING OUT THE QC CHART*, and check the data by the Quality Control Menu screen.

(6) Perform (4) and (5) for APTT, Fbg, and also analyze PT, APTT, and Fbg for QC2 as well.

1.3 QC Error Check

To check quality control errors, you can use a Control Limit method.

Control Limit Method
Error checks are made based on control limits that are set (shown in the table below).

Control Limit	Error Check Method/Action
Upper Flag	If a quality control analysis result exceeds this value, a QC error is generated.
Target	This is the target value for the quality control analysis.
Lower Flag	If a quality control analysis result is below this value, a QC error is generated.

2. QUALITY CONTROL MENU
2.1 Displaying the QC Chart

(1) Press the [SELECT] key to enter the Main Menu screen.

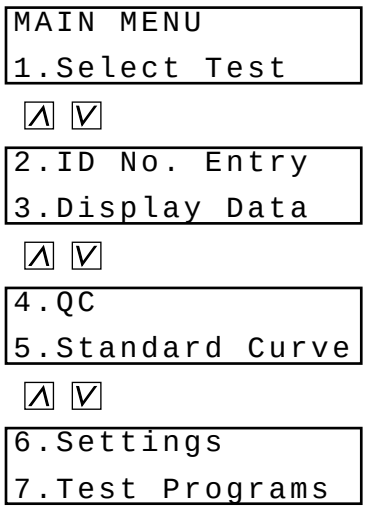

Figure 6-1: Main Menu Screen

(2) Press the [4] key on the Main Menu screen.
The Quality Control Menu screen will appear.
You can scroll the screen up and down by using the [Λ] and [V] keys.

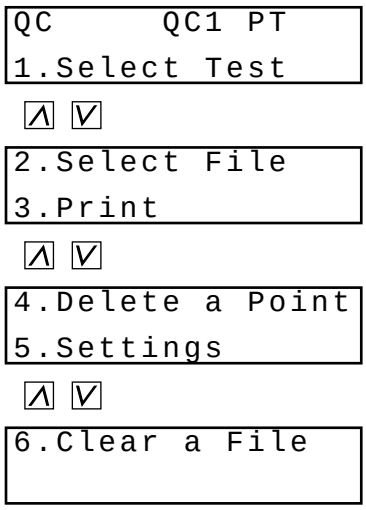

Figure 6-2: Quality Control Menu Screen

Pressing the following key will select each menu function.

[1] key: Moves the screen to the selection of quality control parameters (Select Test).
[2] key: Moves the screen to the selection of quality control files (Select File).
[3] key: Prints out a QC chart (Print).
[4] key: Moves the screen to the deletion of quality control data (Delete a Point).
[5] key: Moves the screen to the quality control settings (Settings).
[6] key: Moves the screen to the deletion of quality control files (Clear a File).
[PRINT] key: Prints out the quality control menu.
[SELECT] key: Returns the screen to the main menu.

3. SELECTING THE QUALITY CONTROL FILE

3.1 Selecting the Quality Control Parameter

Select the quality control parameter for which you wish to perform quality control. "PT" is selected as a default setting.

(1) Press the [1] key on the Quality Control Menu screen.
The Quality Control Parameter Selection screen will appear.

```
Select Test QC1
Test(PT-EX)? PT
```

Figure 6-3: Quality Control Parameter Selection Screen

If you press the [SELECT] key, the display will return to the Quality Control Menu screen (Figure 6-2).

(2) Press the key for the desired parameter, and press the [ENTER] key.
In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key.
In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key.
When you press the [IN] or [EX] key, the Factor Number Entry screen will appear.
When you press any of the other keys, the display will return to the Quality Control Menu screen (Figure 6-2).

```
Select Test QC1
IN(8,9,11,12)? 8
```

Figure 6-4: Factor Number Entry Screen

If you press the [SELECT] key, the display will return to the Quality Control Parameter Selection screen (Figure 6-3).

(3) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12.
In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10.
Then press the [ENTER] key.
The display will return to the Quality Control Menu screen (Figure 6-2).

3.2 Selecting the Quality Control File

Select the file for which you wish to perform quality control. "1" is selected as a default setting.

(1) Press the [2] key on the Quality Control Menu screen.
The Quality Control File Selection screen will appear.

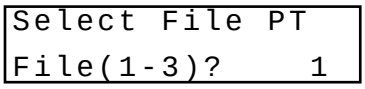

Figure 6-5: Quality Control File Selection Screen

If you press the [SELECT] key, the display will return to the Quality Control Menu screen (Figure 6-2).

(2) Input the file number (any number from 1 to 3) and press the [ENTER] key.
The display will return to the Quality Control Menu screen (Figure 6-2).

4. PRINTING OUT THE QC CHART

You can print out the quality control data and the QC chart concerning the analysis parameters selected in *Section 3.1: Selecting the Quality Control Parameter* and the file selected in *Section 3.2: Selecting the Quality Control File.*

(1) Press the [3] key on the Quality Control Menu screen.
The Printing screen will appear, and the quality control data will be printed out. If the printout is completed, the display will return to the Quality Control Menu screen (Figure 6-2).

```
Printing
Quit:SELECT
```

Figure 6-6: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Quality Control Menu screen (Figure 6-2).

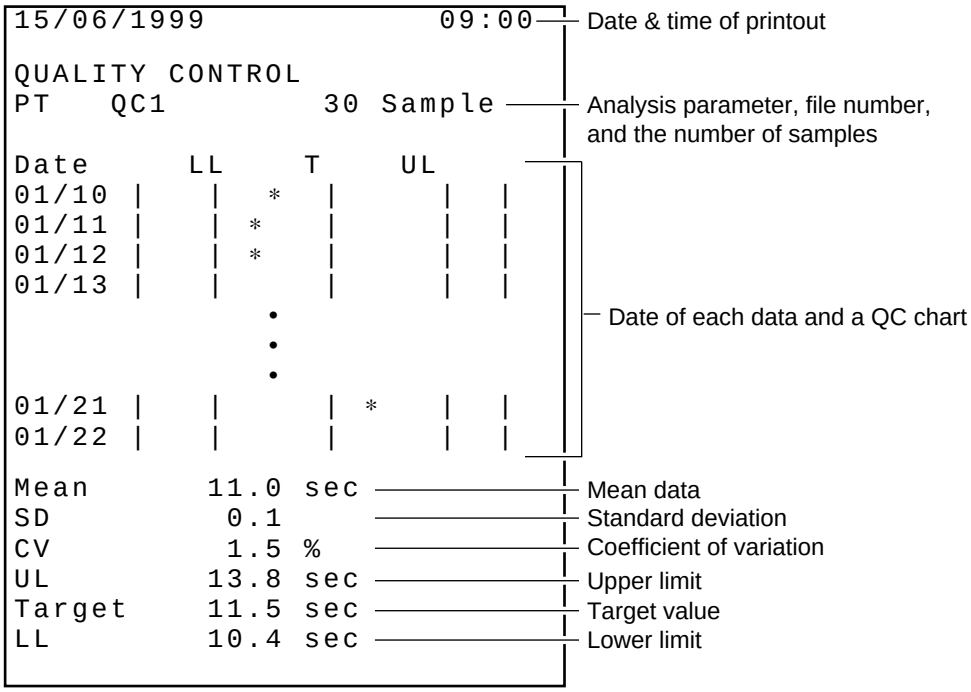

Figure 6-7: Printout Example of Quality Control Data and QC Chart

NOTE:
- "UL", "T", and "LL" shown in Figure 6-7 represent the followings:
  - UL: If the result of the quality control analysis exceeds this value, a quality control error will occur.
  - T: This is the target value for the quality control analysis.
  - LL: If the result of the quality control analysis is below this value, a quality control error will occur.

5. DELETING THE QUALITY CONTROL DATA

5.1 Deleting the Data

You can select and delete particular data from those concerning the analysis parameters selected in *Section 3.1: Selecting the Quality Control Parameter* and the file selected in *Section 3.2: Selecting the Quality Control File.*

CAUTION: • Data that has been deleted cannot be recovered. Carefully verify before deleting data.

(1) Press the [4] key on the Quality Control Menu screen.
The Deleting Data Selection screen will appear.

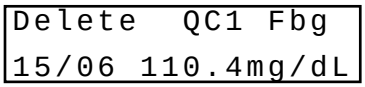

Figure 6-8: Deleting Data Selection Screen

If you press the [SELECT] key, the deletion will be canceled and the display will return to the Quality Control Menu screen (Figure 6-2).

(2) Select the data that you wish to delete by using the [∧] and [∨] keys, and then press the [ENTER] key.
The Deletion Confirmation screen will appear.

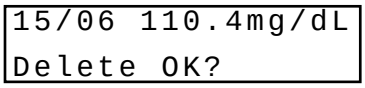

Figure 6-9: Deletion Confirmation Screen

If you press the [SELECT] key, the deletion will be canceled and the display will return to the Quality Control Menu screen (Figure 6-2).

(3) Press the [ENTER] key.
The selected data will be deleted, and the display will return to the Quality Control Menu screen (Figure 6-2).

5.2 Deleting the File

You can delete all the data concerning the analysis parameters selected in *Section 3.1: Selecting the Quality Control Parameter* and the file selected in *Section 3.2: Selecting the Quality Control File*.

CAUTION: • Data that has been deleted cannot be recovered. Carefully verify before deleting data.

NOTE: • All the data concerning the analysis parameter selected will be deleted. The data concerning the other parameters will remain.

(1) Press the [6] key on the Quality Control Menu screen.
The File Confirmation screen will appear.

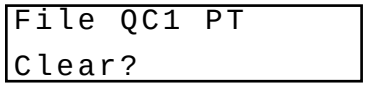

Figure 6-10: File Confirmation Screen

If you press the [SELECT] key, the deletion will be canceled and the display will return to the Quality Control Menu screen (Figure 6-2).

(2) Press the [ENTER] key.
The Deletion Confirmation screen will appear.

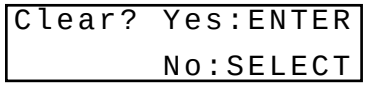

Figure 6-11: Deletion Confirmation Screen

(3) Press the [ENTER] key.
The file will be deleted, and the display will return to the Quality Control Menu screen (Figure 6-2).

6. QUALITY CONTROL SETTINGS

You can perform settings concerning the quality control over the analysis parameters selected in *Section 3.1: Selecting the Quality Control Parameter* and the file selected in *Section 3.2: Selecting the Quality Control File.*

(1) Press the [5] key on the Quality Control Menu screen.
The Control Parameter Selection screen will appear.

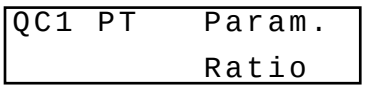

Figure 6-12: Control Parameter Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 6-16) will appear.

(2) Select the desired control parameter by using the [∧] and [∨] keys, and then press the [ENTER] key.
The control parameter will be switched in the order of "analysis parameter" (coagulation time), "Act." ("Conc." in the case of Fbg), "Ratio", "INR", and "DFbg" each time the [∨] key is pressed. Note that only the parameters that have been selected as calculation parameters for the standard curve will be displayed. (See *Chapter 7, Section 6: SETTING THE CALCULATION PARAMETERS*.)

CAUTION: • When you change the control parameter, the saved quality control data will be deleted.

The Upper Limit Entry screen will appear.

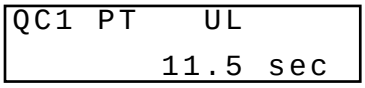

Figure 6-13: Upper Limit Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 6-16) will appear.

(3) Input an upper limit and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The Target Entry screen will appear.

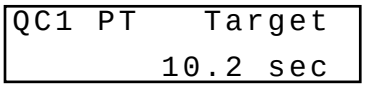

Figure 6-14: Target Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 6-16) will appear.

(4) Input a target and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The Lower Limit Entry screen will appear.

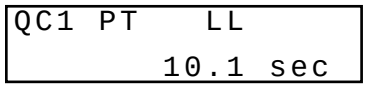

Figure 6-15: Lower Limit Entry Screen

If you press the [ENTER] key, the display will return to the Control Parameter Selection screen (Figure 6-12).

(5) Input a lower limit and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The Update Confirmation screen will appear.

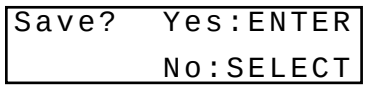

Figure 6-16: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Quality Control Menu screen (Figure 6-2).

(6) Press the [ENTER] key.
The settings will be updated, and the display will return to the Quality Control Menu screen.
When the inputted upper limit is smaller than the lower limit, a setting error will occur. Then an error message will appear on the screen and an alarm will sound.

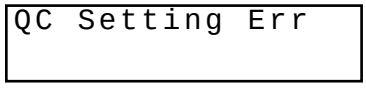

Figure 6-17: Error Notice Screen

If you press the [C] key, the alarm will stop and the Upper Limit Entry screen (Figure 6-13) will appear. Then go back to step (3) and input the upper and lower limits again.

NOTE:
- "UL", "Target", and "LL" shown in Figures 6-13, 6-14 and 6-15 represent the followings:
  - UL: If the result of the quality control analysis exceeds this value, a quality control error will occur.
  - Target: This is the target value for the quality control analysis.
  - LL: If the result of the quality control analysis is below this value, a quality control error will occur.

CHAPTER 7 SETTING STANDARD CURVES

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   - 6.5 Setting the DFbg 7-16
   - 6.6 Printing Out the Calculation Parameter Settings 7-17

7. DELETING THE STANDARD CURVE DATA 7-18

1. INTRODUCTION

A standard curve is a parameter that is used to calculate the calculation parameters based on the coagulation time and dOD obtained by analysis.

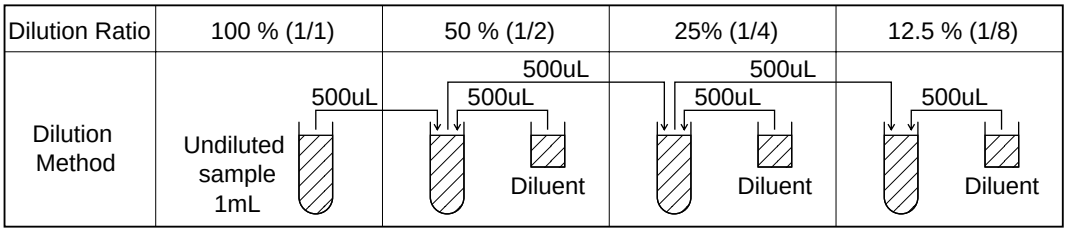
CAUTION • The standard curve determines the accuracy of calculation parameters. Prepare proper standard curves for the reagents be used.

2. OBTAINING DATA FOR STANDARD CURVE

In order to obtain standard curve data, let the instrument analyze the sample whose activity percent or concentration has been determined beforehand.

The following are explained as an example of analyzing PT, Fbg, TTO, and NT respectively by four points.

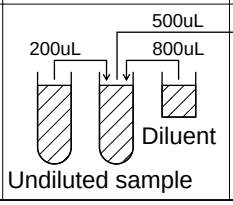
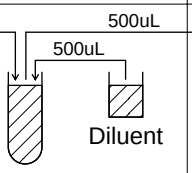
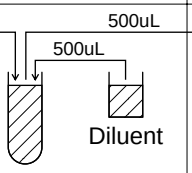
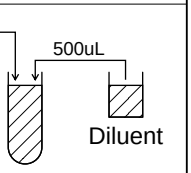
In the case of PT



(1) Prepare 1 mL of sample whose activity percent has been determined.
(2) Mix the diluent (500 μL) and the sample (500 μL) to make 50% sample.
(3) Mix the diluent (500 μL) and the sample made in step (2) (500 μL), to make 25% sample.
(4) Mix the diluent (500 μL) and the sample made in step (3) (500 μL), to make 12.5% sample.
(5) Dispense 50 μL of sample for each dilution ratio into reaction tubes, and perform an analysis.
(6) Input standard curve data based on the printed analysis results.
For the method of inputting the data, see *Section 4: PREPARING THE STANDARD CURVE*.
(7) Print out the prepared standard curve for verification.
For the method of printing out the standard curve, see *Section 5: PRINTING OUT THE STANDARD CURVE*. If an abnormality is found in the standard curve, go back to step (1) and try the same procedure.

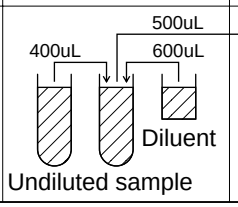
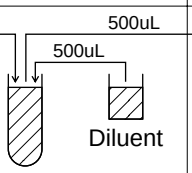
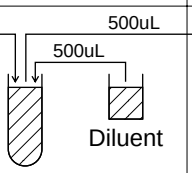
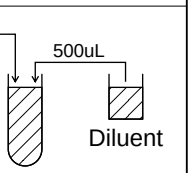
CAUTION: • When you use commercially available calibrator plasma or a calibrator packed in a reagent kit, follow the instruction in the manual attached to it.

In the case of Fbg

Dilution Ratio	200 % (2/1)	100 % (1/1)	50 % (1/2)	25 % (1/4)
Dilution Method				

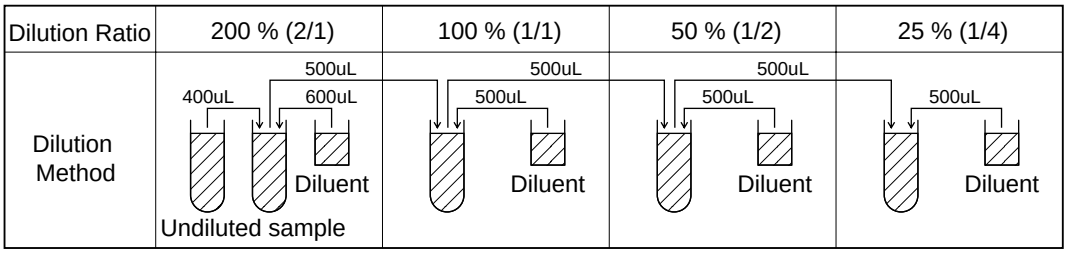
(1) Prepare 200 μL of sample whose concentration has been determined.
(2) Mix the diluent (800 μL) and the sample (200 μL) to make 200% sample.
(3) Mix the diluent (500 μL) and the sample made in step (2) (500 μL), to make 100% sample.
(4) Mix the diluent (500 μL) and the sample made in step (3) (500 μL), to make 50% sample.
(5) Mix the diluent (500 μL) and the sample made in step (4) (500 μL), to make 25% sample.
(6) Dispense 100 μL of sample for each dilution ratio into reaction tubes, and perform an analysis.
(7) Input standard curve data based on the printed analysis results.
For the method of inputting the data, see *Section 4: PREPARING THE STANDARD CURVE*.
(8) Print out the prepared standard curve for verification.
For the method of printing out the standard curve, see *Section 5: PRINTING OUT THE STANDARD CURVE*. If an abnormality is found in the standard curve, go back to step (1) and try the same procedure.

In the case of TTO

Dilution Ratio	100 % (1/1)	50 % (1/2)	25 % (1/4)	12.5 % (1/8)
Dilution Method				

(1) Prepare 400 μL of sample whose activity percent has been determined.
(2) Mix the diluent (600 μL) and the sample (400 μL) to make 100% sample.
(3) Mix the diluent (500 μL) and the sample made in step (2) (500 μL), to make 50% sample.
(4) Mix the diluent (500 μL) and the sample made in step (3) (500 μL), to make 25% sample.
(5) Mix the diluent (500 μL) and the sample made in step (4) (500 μL), to make 12.5% sample.
(6) Dispense 50 μL of sample for each dilution ratio into reaction tubes, and perform an analysis.
(7) Input standard curve data based on the printed analysis results.
For the method of inputting the data, see *Section 4: PREPARING THE STANDARD CURVE*.
(8) Print out the prepared standard curve for verification.
For the method of printing out the standard curve, see *Section 5: PRINTING OUT THE STANDARD CURVE*. If an abnormality is found in the standard curve, go back to step (1) and try the same procedure.

In the case of NT



(1) Prepare 400 μL of sample whose activity percent has been determined.
(2) Mix the diluent (600 μL) and the sample (400 μL) to make 200% sample.
(3) Mix the diluent (500 μL) and the sample made in step (2) (500 μL), to make 100% sample.
(4) Mix the diluent (500 μL) and the sample made in step (3) (500 μL), to make 50% sample.
(5) Mix the diluent (500 μL) and the sample made in step (4) (500 μL), to make 25% sample.
(6) Dispense 50 μL of sample for each dilution ratio into reaction tubes, and perform an analysis.
(7) Input standard curve data based on the printed analysis results.
For the method of inputting the data, see *Section 4: PREPARING THE STANDARD CURVE*.
(8) Print out the prepared standard curve for verification.
For the method of printing out the standard curve, see *Section 5: PRINTING OUT THE STANDARD CURVE*. If an abnormality is found in the standard curve, go back to step (1) and try the same procedure.

3. STANDARD CURVE MENU

(1) Press the [SELECT] key to enter the Main Menu screen.

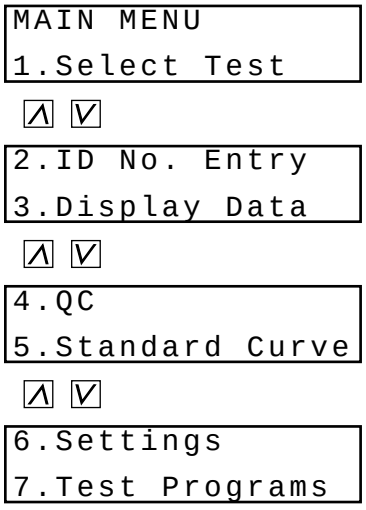


Figure 7-1: Main Menu Screen

(2) Press the [5] key on the Main Menu screen.
The Standard Curve Menu screen will appear.
You can scroll the menu up and down by using the [Λ] and [V] keys.

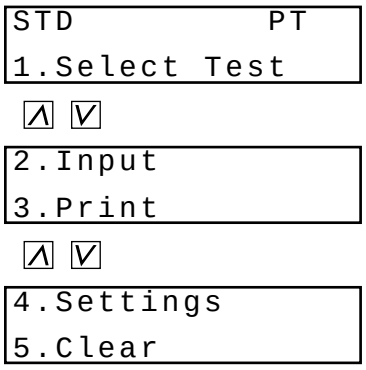


Figure 7-2: Standard Curve Menu Screen

Pressing the following key will select each menu function.

[1] key:	Moves the screen to the selection of analysis parameters (Select Test).
[2] key:	Moves the screen to the entry of standard curve data (Input).
[3] key:	Prints out the standard curve (Print).
[4] key:	Displays the calculation parameter setting menu (Settings).
[5] key:	Moves the screen to the deletion of the standard curve data (Clear).
[PRINT] key:	Prints out the standard curve menu.
[SELECT] key:	Returns the screen to the main menu.

CAUTION:
- You cannot use the [2], [3], and [5] keys when you have not selected calculation parameters in *Section 6: SETTING THE CALCULATION PARAMETERS.*

4. PREPARING THE STANDARD CURVE

Prepare a standard curve, based on the data obtained in *Section 2: OBTAINING DATA FOR STANDARD CURVE*.

4.1 Selecting the Analysis Parameter

Select the analysis parameter for which you wish to prepare the standard curve. "PT" is selected as a default setting.

(1) Press the [1] key on the Standard Curve Menu screen.
The Analysis Parameter Selection screen will appear.

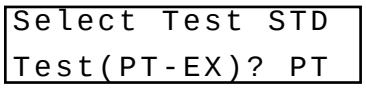


Figure 7-3: Analysis Parameter Selection Screen

If you press the [SELECT] key, the display will return to the Standard Curve Menu screen (Figure 7-2).

(2) Press the key for the desired parameter, and press the [ENTER] key.
In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key.
In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key.
When you press the [IN] or [EX] key, the Factor Number Entry screen will appear.
When you press any of the other keys, the display will return to the Standard Curve Menu screen (Figure 7-2).

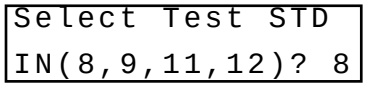


Figure 7-4: Factor Number Entry Screen

If you press the [SELECT] key, the display will return to the Analysis Parameter Selection screen (Figure 7-3).

(3) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12.
In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10.
Then press the [ENTER] key.
The display will return to the Standard Curve Menu screen (Figure 7-2).

4.2 Inputting the Standard Curve Data

Input the following standard curve data concerning the parameter selected in *Section 4.1: Selecting the Analysis Parameter*. Items to be inputted will vary depending on the settings set in *Section 6: SETTING THE CALCULATION PARAMETERS.*

- Activity percent (concentration) and coagulation time:
  You can input data up to 6 points. Input 2 points at least.
- Normal:
  This is the value to calculate the ratio. This parameter is available when the ratio or the INR is selected as a calculation parameter.
- ISI:
  This is the value to calculate the INR. This parameter is available when the INR is selected as a calculation parameter.
- Standard concentration and dH:
  This is the value to calculate the DFbg. This parameter is available when the DFbg is selected as a calculation parameter.

CAUTION:
- If the ratio is not selected as a calculation parameter but the INR has been selected, the Normal Value Entry screen will appear. However, neither the display of the ratio nor the print of data are performed in this case.

(1) Press the [2] key on the Standard Curve Menu screen.
The Activity Percent (Concentration) & Coagulation Time Entry screen will appear.

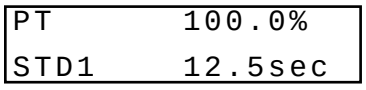


Figure 7-5: Activity Percent (Concentration) & Coagulation Time Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 7-9) will appear.

(2) Input activity percent (concentration) and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
Then input coagulation time and press the [ENTER] key. If you do not change the value, press the [ENTER] key only.
Each time the [ENTER] key is pressed twice, the item will be switched in the order of "STD1", "STD2", "STD3", "STD4", "STD5", and "STD6". The values should be inputted in decreasing order of concentration, from STD1 to STD 6.
When you input the value for STD6 and press the [ENTER] key, the Normal Value Entry screen (Figure 7-6) will appear depending on the calculation parameter settings. When none of these calculation parameters has been selected, the display will return to the screen to input the value for STD1. For default values, see *Appendix B.*

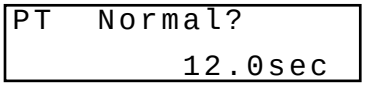


Figure 7-6: Normal Value Entry Screen

- This parameter will be displayed only when you have selected the ratio or the INR as a calculation parameter.
- If you press the [SELECT] key, the Update Confirmation screen (Figure 7-9) will appear.

CAUTION:
- Input is permitted to the decimal places shown below:
  - Activity %, mg/dL, IU, and time: One decimal place
  - g/L: Three decimal places
  - ISI: Two decimal places

(3) Input a normal value and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
Depending on the calculation parameter settings, either the ISI Entry (Figure 7-7) or the Standard Concentration & dH Entry screen (Figure 7-8) screen will appear. If neither of these calculation parameters has been selected, the display will return to the Activity Percent (Concentration) & Coagulation Time Entry screen (Figure 7-5).

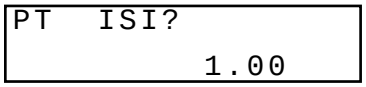


Figure 7-7: ISI Entry Screen

- This parameter will be displayed only when you have selected the INR as a calculation parameter.
- If you press the [SELECT] key, the Update Confirmation screen (Figure 7-9) will appear.

(4) Input an ISI and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
Depending on the calculation parameter settings, the Standard Concentration & dH Entry screen will appear. If this parameter has not been selected, the display will return to the Activity Percent (Concentration) & Coagulation Time Entry screen (Figure 7-5).

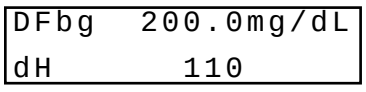


Figure 7-8: Standard Concentration & dH Entry Screen

- This parameter will be displayed only when you have selected the DFbg as a calculation parameter.
- If you press the [SELECT] key, the Update Confirmation screen (Figure 7-9) will appear.

(5) Input the standard concentration and dH, and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The display will return to the Activity Percent (Concentration) & Coagulation Time Entry screen (Figure 7-5).

CAUTION: • When you have inputted a wrong value, go back to the first step and input the value again.

(6) Press the [SELECT] key.
The Update Confirmation screen will appear.

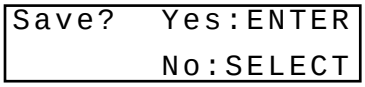


Figure 7-9: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Standard Curve Menu screen (Figure 7-2).

(7) Press the [ENTER] key.
The settings will be updated, and the display will return to the Standard Curve Menu screen (Figure 7-2).
If there is an error in the settings, an error message will appear on the screen and an alarm will sound.

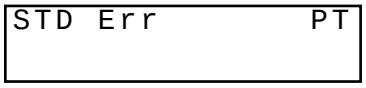


Figure 7-10: Error Notice Screen

If you press the [C] key, the alarm will stop and the display will return to the Activity Percent (Concentration) & Coagulation Time Entry screen (Figure 7-5).

5. PRINTING OUT THE STANDARD CURVE

Print out the content of standard curve settings for the parameter selected in *Section 4.1: Selecting the Analysis Parameter.*

(1) Press the [3] key on the Standard Curve Menu screen.
The Printing screen will appear and the printout of the content of standard curve settings will start. The subject of the printout is limited to the calculation parameters selected in *Section 6: SETTING THE CALCULATION PARAMETER.* When the printout is completed, the display will return to the Standard Curve Menu screen (Figure 7-2).

```
Printing
Quit:SELECT
```

Figure 7-11: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Standard Curve Menu screen (Figure 7-2).

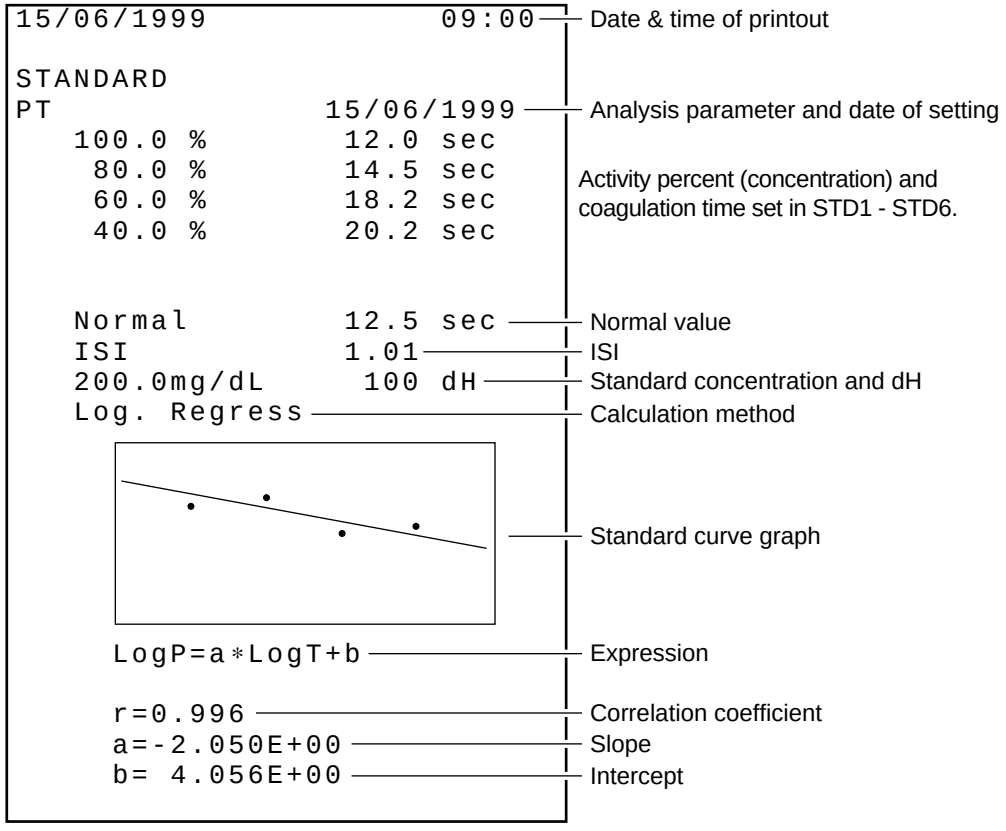


Figure 7-12: Printout Example of Standard Curve

6. SETTING THE CALCULATION PARAMETERS

Set the calculation parameter for the analysis parameter selected in *Section 4.1: Selecting the Analysis Parameter*.

6.1 Calculation Parameter Setting Menu

If you press the [4] key on the Standard Curve Menu screen, the Calculation Parameter Setting Menu screen will appear.
You can scroll the menu up and down by using the [Λ] and [V] keys.

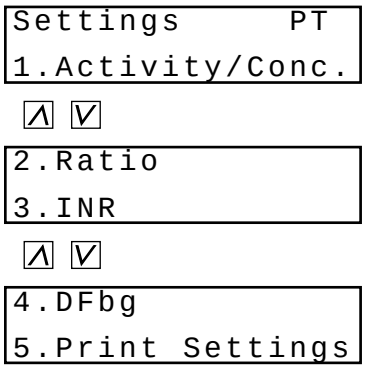


Figure 7-13: Calculation Parameter Setting Menu Screen

Pressing the following key will select each menu function.
[1] key: Moves the screen to the setting of activity percent and concentration.
[2] key: Moves the screen to the setting of ratio.
[3] key: Moves the screen to the setting of INR.
[4] key: Moves the screen to the setting of DFbg. (Can be used in the case of PT.)
[5] key: Prints out the calculation parameter setting.
[PRINT] key: Prints out the calculation parameter setting menu.
[SELECT] key: Returns the screen to the standard curve menu.

6.2 Setting the Activity Percent and Concentration

Set whether to use the activity percent (concentration in the case of Fbg) as a calculation parameter.

(1) Press the [1] key on the Calculation Parameter Setting Menu screen.
The ON/OFF Selection screen will appear.

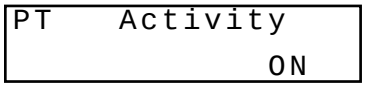


Figure 7-14: ON/OFF Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 7-17) will appear.

(2) Select whether to use the activity percent (concentration in the case of Fbg) by using the [Λ] and [V] keys, and then press the [ENTER] key.
The display will be switched between "ON (use)" and "OFF (do not use)" each time the [V] key is pressed.
When "ON" is selected, the Unit Selection screen will appear.

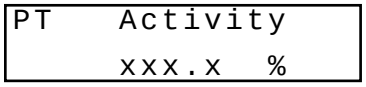


Figure 7-15: Unit Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 7-17) will appear.

(3) Select the desired unit by using the [Λ] and [V] keys, and press the [ENTER] key.
The display will be switched in the order of "xxx.x %", "xxx.x mg/dL", "x.xxx g/L", "xx.xx –", and "x.xxx IU" each time the [V] key is pressed.
The Calculation Method Selection screen will appear.

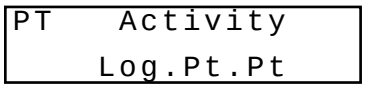


Figure 7-16: Calculation Method Selection Screen

If you press the [ENTER] key, the display will return to the ON/OFF Selection screen (Figure 7-14).

(4) Select the desired calculation method by using the [Λ] and [V] keys, and press the [SELECT] key.
The display will be switched in the order of "Log. Pt. Pt", "Log. Regress", "Lin. Regress" each time the [V] key is pressed.
The Update Confirmation screen will appear.

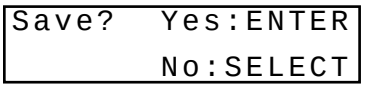


Figure 7-17: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

(5) Press the [ENTER] key.
The settings will be updated and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

6.3 Setting the Ratio

Set whether to use the ratio as a calculation parameter.

(1) Press the [2] key on the Calculation Parameter Setting Menu screen.
The ON/OFF Selection screen will appear.

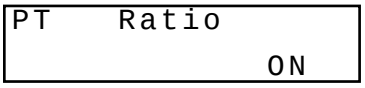


Figure 7-18: ON/OFF Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 7-19) will appear.

(2) Select whether to use the ratio by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched between "ON (use)" and "OFF (do not use)" each time the [∨] key is pressed.
The Update Confirmation screen will appear.

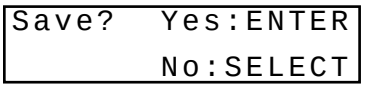


Figure 7-19: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

(3) Press the [ENTER] key.
The settings will be updated and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

6.4 Setting the INR

Set whether to use the INR as a calculation parameter.

(1) Press the [3] key on the Calculation Parameter Setting Menu screen.
The ON/OFF Selection screen will appear.

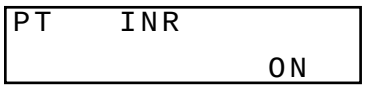


Figure 7-20: ON/OFF Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 7-22) will appear.

(2) Select whether to use the INR by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched between "ON (use)" and "OFF (do not use)" each time the [∨] key is pressed.
The Unit Selection screen will appear.

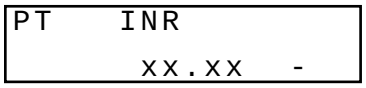


Figure 7-21: Unit Selection Screen

If you press the [ENTER] key, the display will return to the ON/OFF Selection screen (Figure 7-20).

(3) Select the desired unit by using the [∧] and [∨] keys, and press the [SELECT] key.
The display will be switched between "xx.xx –" and "xx.xx INR" each time the [∨] key is pressed.
The Update Confirmation screen will appear.

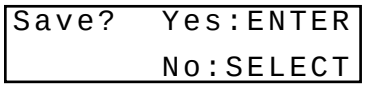


Figure 7-22: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

(4) Press the [ENTER] key.
The settings will be updated and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

6.5 Setting the DFbg

Set whether to use the DFbg as a calculation parameter.

(1) Press the [4] key on the Calculation Parameter Setting Menu screen.
The ON/OFF Selection screen will appear.

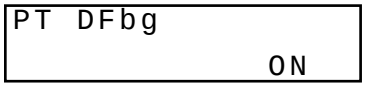


Figure 7-23: ON/OFF Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 7-25) will appear.

(2) Select whether to use the DFbg by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched between "ON (use)" and "OFF (do not use)" each time the [∨] key is pressed.
The Unit Selection screen will appear.

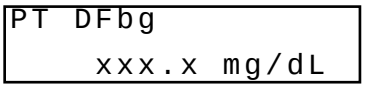


Figure 7-24: Unit Selection Screen

If you press the [ENTER] key, the display will return to the ON/OFF Selection screen (Figure 7-23).

(3) Select the desired unit by using the [∧] and [∨] keys, and press the [SELECT] key.
The display will be switched between "xxx.x mg/dL" and "x.xxx g/L" each time the [∨] key is pressed.
The Update Confirmation screen will appear.

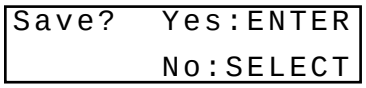


Figure 7-25: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

(4) Press the [ENTER] key.
The settings will be updated and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

6.6 Printing Out the Calculation Parameter Settings

Print out the contents of the calculation parameter settings.

(1) Press the [5] key on the Calculation Parameter Setting Menu screen.
The Printing screen will appear and printout of the calculation parameter settings will start. When the printout is completed, the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

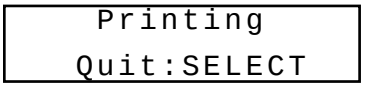


Figure 7-26: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

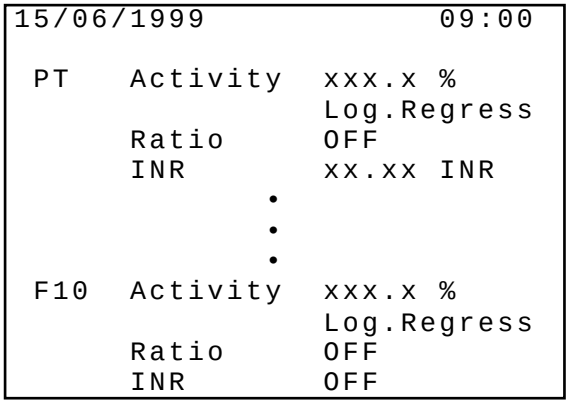


Figure 7-27: Printout Example of Calculation Parameter Settings

7. DELETING THE STANDARD CURVE DATA

Delete the standard curve data concerning the analysis parameter selected in *Section 4.1: Selecting the Analysis Parameter.*

(1) Press the [5] key on the Standard Curve Menu screen.
The Deleting Data Confirmation screen will appear.

Figure 7-28: Deleting Data Confirmation Screen

If you press the [SELECT] key, the deletion will be canceled and the display will return to the Standard Curve Menu screen (Figure 7-2).

(2) Press the [ENTER] key.
The Deletion Confirmation screen will appear.

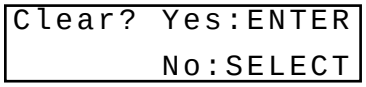


Figure 7-29: Deletion Confirmation Screen

(3) Press the [Enter] key.
The data will be deleted and the display will return to the Standard Curve Menu screen (Figure 7-2).

CHAPTER 8 TROUBLESHOOTING

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1. INTRODUCTION

This chapter explains the error messages that are displayed by the CA-50, as well as failures that can occur and the corrective action for the operator to take if a failure occurs. If the instrument does not return to the normal operating condition even after you have taken the action described in this chapter, contact your Sysmex service representative for assistance.
This chapter will principally cover the content listed below.

Troubleshooting by Error Message
This section provides a list of the error messages that can appear on the screen when a problem occurs. It also explains the corrective action to take.

Instrument Check
This section explains how to test whether the instrument is operating properly.

2. WHEN YOU SUSPECT AN ERROR

Table 8-1: Check Items When You Suspect an Error

1. Turning the power ON does not start the instrument.	• Is the power cord connected securely? • Is the fuse blown? Refer to *Chapter 5, Section 5.1: Replacing Fuses*. • Is the power supplied to AC outlet?
2. When the power is ON, nothing is displayed and "beep" keeps sounding.	• There is a possibility that memory error has occurred. Turn OFF the power, and turn it ON again 1 - 2 minutes later.
3. The screen displays nothing.	• Is LCD brightness properly adjusted? Refer to *Appendix A, Section 7: Adjusting the LCD Brightness*.
4. An error occurs.	• Refer to *Section 3: TROUBLESHOOTING BY ERROR MESSAGE* in this chapter.

3. TROUBLESHOOTING BY ERROR MESSAGE

3.1 Troubleshooting Guide

The errors that appear on the screen are classified as shown below.

Instrument Errors (in analysis mechanism, temperature adjustment, etc.)

- If an instrument error occurs, an error message will appear on the screen and an alarm will sound. To stop the alarm, press the [C] key.

CAUTION:	• When an error occurs, the alarm will keep sounding and the error message will be displayed on the screen until the [C] key is pressed.

- Analysis operation will stop when an instrument error occurs. Take corrective actions shown in this chapter.
  If the error is not corrected even after you have taken the prescribed corrective actions, contact your Sysmex service representative.

Analysis Data Errors

- If an analysis data error occurs, an error message will be printed on the printout of analysis results. When the printout by the graph or analysis format is selected, an error code (ERR xxx) will also be printed.
- "*" will be added to the data of sample on which an error occurs.
- Reanalysis is required for the parameter whose analysis was interrupted due to an instrument error, and for the parameter on which an analysis data error occurs.

3.2 Instrument Errors and Corrective Actions

Table 8-2: Instrument Errors and Corrective Actions

Error Message		Probable Cause	Corrective Action
Screen	Printout		
BBURAM Error (QC File)/ (Measurement)	BBURAM Error (QC File)/ (Measurement)	An error occurred in the quality control data etc.	Check the quality control data. Turn OFF the power, wait a few seconds, and then turn it ON again. If the error recurs, contact your Sysmex service representative.
EEPROM Error (Service)/ (Settings)/ (STD)	EEPROM Error (Service)/ (Settings)/ (STD)	There is an error in the settings.	Check the settings. Turn OFF the power, wait a few seconds, and then turn it ON again. If the error recurs, contact your Sysmex service representative.
HC ACK Code Error	HC ACK Code Error	ACK cannot be received from the host computer.	Check the operation of the host computer and the condition of the connection cable. Re-output the data from the Display Data screen that displays detailed analysis results.
HC Communication Error	HC Communication Error	The communication with host computer is abnormal.	Check the operation of the host computer and the condition of the connection cable. Re-output the data from the Display Data screen that displays detailed analysis results.
HC CTS Time Out	HC CTS Time Out	The host computer is not ready for receiving signals. The host computer did not respond within the prescribed time-out time (5 sec.).	Check the operation of the host computer and the condition of the connection cable. Re-output the data from the Display Data screen that displays detailed analysis results.
HC Off Line	HC Off Line	The connection cable is disconnected. Host computer's power is OFF. The host computer is not ready for receiving signals.	Check that the cable is securely connected. Turn ON the host computer. Check the operation of the host computer. Re-output the data from the Display Data screen that displays detailed analysis results.
HC Reception Count Error	HC Reception Count Error	The reception of the NAK from the host computer exceeded the limit.	Check the operation of the host computer and the condition of the connection cable. Re-output the data from the Display Data screen that displays detailed analysis results.
HC Transmission Count Error	HC Transmission Count Error	The number of re-transmission to the host computer exceeded the limit.	Check the operation of the host computer and the condition of the connection cable. Re-output the data from the Display Data screen that displays detailed analysis results.

Error Message		Probable Cause	Corrective Action
Screen	Printout		
Lid Open CH # *1	Lid Open CH # *1	The pipette guide was opened during analysis. Or, the pipette guide was not closed within two seconds after a reagent is added. Or, the pipette guide is opened in the Ready status over 15 minutes. (Excluding the operation in QC menu, Standard Curve menu, Settings menu and System Tests menu)	Discard the reaction tube in the detector and re-analyze the sample. Or, close the pipette guide.
Measurement Stop CH# *1	Measurement Stop CH# *1	The [Start] switch is pressed again until the analysis completion.	Analyze from the beginning again.
Paper Empty	---	Paper is not set in the printer or runs out.	Replenish paper.
Printer Error	----	The build-in printer clogged up.	Reset the paper in the printer.
QC Err++	QC Err++	Results of quality control analysis exceeded the upper limit.	Check control plasma and reagents.
QC Err-	QC Err-	Results of quality control analysis exceeded the lower limit.	Check control plasma and reagents.
QC Setting Err	QC Setting Err	Abnormal quality control setting is inputted.	Re-input a setting value.
RAM Error	RAM Error	The computer is faulty.	Turn OFF the power, wait a few seconds, and then turn it ON again. If the error recurs, contact your Sysmex service representative.
Reagent Err CH # *1	Reagent Err CH # *1	Reagent was not added within the allowed time.	Discard the reaction tube in the detector and re-analyze the sample.
ROM Error	ROM Error	The program was not loaded successfully.	Turn OFF the power, wait a few seconds, and then turn it ON again. If the error recurs, contact your Sysmex service representative.
STD Err ## *2	STD Err ## *2	Abnormal standard curve data is inputted.	Re-input standard curve data, or obtain correct data by re-analysis.
Temperature Err (Reagent)	Temperature Err (Reagent)	The temperature at the incubator was out of the control limit after "Ready", or the incubator is faulty.	If the error recurs, contact your Sysmex service representative.
Temperature Err CH # *1	Temperature Err CH # *1	The temperature at the detector was out of the control limit during analysis, or the detector is faulty.	If the error recurs, contact your Sysmex service representative.

*1: # shows the channel number (1 - 4) on which an error occurs.
*2: ## shows the name of the parameter in question .

3.3 Analysis Data Errors and Corrective Actions

Table 8-3: Analysis Data Errors and Corrective Actions

Error Code	Message	Probable Cause	Corrective Action
ERR 1	Temp Error Occur	The temperature at the incubator or detector was out of the control limit, or the incubator or detector is faulty.	See "Temperature Err" in *Section 3.2: Instrument Errors and Corrective Actions.*
ERR 2	Slight Coagulation	Detected coagulation reaction is very weak. This error typically occurs if the sample is abnormal, e.g. low fibrinogen, or if a reagent problem exists.	The following steps should be taken: 1)Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc. 2)Verify delivery of sample and reagent. 3)Review the analysis data for clot formation. A weak clot formation may be due to an abnormally low fibrinogen level, factor deficiencies, or the presence of inhibitors. 4)Re-analyze the sample. 5)Upon repeating, if "Slight Coagulation" occurs again, review the previous patient history to determine acceptability of patient results. 6)Results of the other parameters considered, then make overall evaluation. Follow your laboratory's alternate protocol. (When analysis parameter is APTT. *1)
ERR 4	Analysis Time Over	Coagulation was not completed within the prescribed detection time. The situation occurs when testing samples with prolonged clotting times.	Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc. And verify delivery of sample and reagent. When re-analyze the sample, if that given a same message again, the sample may not be capable of forming a firm clot. Review the previous patient history to determine acceptability of patient results. Results of the other parameters considered, then make overall evaluation. Follow your laboratory's alternate protocol.

CAUTION • *1: When analysis parameter is APTT
If the time in the "2%" position is equal to or less than 15 seconds, then an abnormal early reaction may be occurred. In addition, if re-analyzed result is the same, it should not be reported. Results of the other parameters considered, then make overall evaluation.
See *Chapter 1, Section 4: ANALYSIS PARAMETERS AND CALCULATION PARAMETERS* and refer to *"Interpretation of APTT Abnormal Early Reaction"*.

Error Code	Message	Probable Cause	Corrective Action
ERR 8	Coag. Curve Error	Coagulation curve is unexpected fluctuation. 1)Slope drops in areas. 2)Slope is too steep in areas. 3)Abnormality has occurred on the coagulation time for Fbg etc. due to air bubbles caused by cold buffer (Owren's Veronal Buffer). 4)The air bubbles mixed when the reagent was added to the reaction tube.	The following steps should be taken: 1)Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc. 2)Verify delivery of sample and reagent. 3)Review the analysis data for clot formation. 4)Re-analyze the sample. 5)Upon repeating, if "Coag. Curve Error" occurs again, review the previous patient history to determine acceptability of patient results. 6)Results of the other parameters considered, then make overall evaluation. Follow your laboratory's alternate protocol. (When analysis parameter is APTT. *1)
ERR 16	Turbidity Level Over	Turbidity was too high to allow analysis.	Dilute and re-analyze.
ERR 32	No Coagulation	Coagulation was not detected.	The following steps should be taken: 1)Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc. 2)Verify delivery of sample and reagent. 3) [dH ≥ 10: *2] • Review the analysis data for clot formation. A weak clot formation may be due to an abnormally low fibrinogen level, factor deficiencies, or the presence of inhibitors. • Re-analyze the sample. • Review the previous patient history to determine acceptability of patient results. • Results of the other parameters considered, then make overall evaluation. • Follow your laboratory's alternate protocol. (When analysis parameter is APTT. *1) [dH <10: *2] •Review the original graph to determine if clotting occurred.(The analysis data will not print, if dH < 10) • Re-analyze the sample. • Upon repeating, if "No Coagulation" occurs again, review the previous patient history to determine acceptability of patient results. • Results of the other parameters considered, then make overall evaluation. • Follow your laboratory's alternate protocol.

⚠ CAUTION

- *1: When analysis parameter is APTT
  If the time in the "2%" position is equal to or less than 15 seconds, then an abnormal early reaction may be occurred. In addition, if re-analyzed result is the same, it should not be reported. Results of the other parameters considered, then make overall evaluation.
  See *Chapter 1, Section 4: ANALYSIS PARAMETERS AND CALCULATION PARAMETERS* and refer to *"Interpretation of APTT Abnormal Early Reaction"*.

NOTE:

- *2 For the procedure to observe dH: Amount of scattered light change in reactive process, see Chapter 4, Section 2.2: Printing Out Analysis Results.

Error Code	Message	Probable Cause	Corrective Action
ERR 64	Analysis Failed	The pipette guide was opened during photo detection, or reagent was not added within the allowed time. Or, the analysis start switch was pressed again before analysis completion but after starting the analysis.	See "Lid Open", "Reagent Err" and "Measurement Stop" in *Section 3.2: Instrument Errors and Corrective Actions.*
ERR100	Range Over	Variation of reaction curve is extremely high. This error message may indicate that the PT result was <7 seconds, or the APTT result was <15 seconds, or the Fbg result was <3 seconds.	Check the sample, reagents and instrument condition. Review the analysis data for clot formation. If these conditions are acceptable, re-analyze the sample and review the previous patient history to determine acceptability of patient results. Results of the other parameters considered, then make overall evaluation. Follow your laboratory's alternate protocol.

CAUTION:

- When two or more errors occur simultaneously, the error code will be shown by the sum of error codes. (ERR 16, 32, and 64 can occur simultaneously only with the ERR 1, Temperature Error.) For example, when the Temperature Error and the Turbidity Level Over occur simultaneously, the error code to be displayed will be ERR 17.

4. INSTRUMENT CHECK

This section explains how to check the instrument to see that it is operating properly.

4.1 Test Program Menu

(1) Press the [SELECT] key to enter the Main Menu screen.

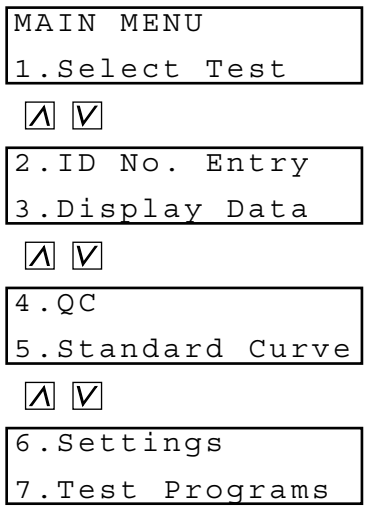

Figure 8-1: Main Menu Screen

(2) Press the [7] key on the Main Menu screen.
The Test Program Menu screen will appear.
You can scroll the menu up and down by using the [Λ] and [V] keys.

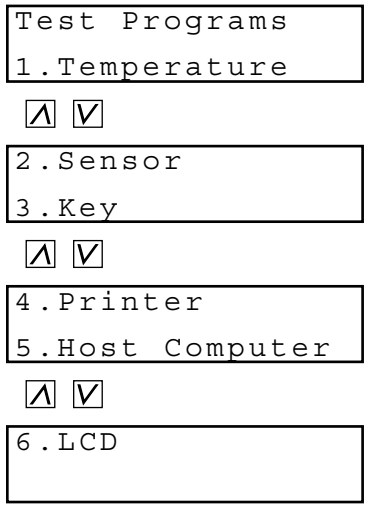

Figure 8-2: Test Program Menu Screen

Pressing the following key will select each menu function.

[1] key:	Moves the screen to the display of temperatures (Temperature).
[2] key:	Moves the screen to the sensor test (Sensor).
[3] key:	Moves the screen to the key entry test (Key).
[4] key:	Moves the screen to the built-in printer test (Printer).
[5] key:	Moves the screen to the communication test (Host Computer).
[6] key:	Moves the screen to the LCD screen test (LSD).
[PRINT] key:	Prints out the test program menu.
[SELECT] key:	Returns the screen to the main menu.

4.2 Display of Temperatures

Check the temperatures at the detector and the incubator. (Temperatures are shown in °C.) When Ready status, the temperature of each channel's detector is usually 37°C ± 0.5°C, and the temperature of the incubator is 37°C ± 1°C.

(1) Press the [1] key on the Test Program Menu screen.
The Temperature Display screen will display the temperature at each channel's detector.

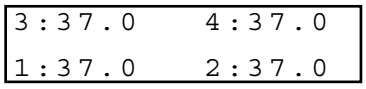

Figure 8-3: Temperature Display Screen 1

(2) Press the [V] key.
The screen will display the temperatures at the incubator and in the room.

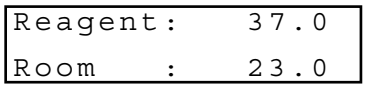

Figure 8-4: Temperature Display Screen 2

If you press the [SELECT] key, the display will return to the Test Program Menu screen (Figure 8-2).

4.3 Sensor Test

Test the sensor that detects the closing and opening of the pipette guide, and the addition of reagents.

(1) Press the [2] key on the Test Program Menu screen.
The Sensor Test screen will appear.

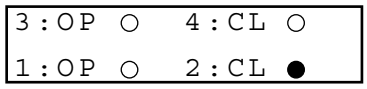

Figure 8-5: Sensor Test Screen

- OP: Pipette guide is opened.
- CL: Pipette guide is closed.
- ○: Addition of reagent is not detected.
- ●: Addition of reagent is detected.

(2) Open and close each pipette guide, and check that the sensor correctly detects the closing and opening.

(3) Set a reaction tube in each channel and add 100 µL of Owren's Veronal Buffer with a pipette. Check that the sensor correctly detects the addition of Owren's Veronal Buffer. The display will change from "○" to "●", and the detector LED will change from green to red.

(4) Press the [Start] switch of each channel to activate the mixing motor.

(5) Press the [C] key to reset all channels.
The display will change from "●" to "○", and the detector LED will change from red to green.

(6) Press the [SELECT] key.
The detector LED will return to the original condition, and the display will return to the Test Program Menu screen (Figure 8-2).

NOTE: • If you press the [V] key on the Sensor Test screen, you can see the version of the program. To return to the previous screen, press the [Λ] or the [V] key.

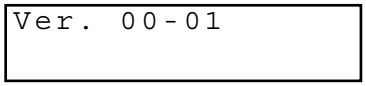

Figure 8-6: Program Version Display Screen

4.4 Key Entry Test

Check the input keys to see that they are operating properly.

(1) Press the [3] key on the Test Program Menu screen.
The Key Entry Test screen will appear.

(2) Press any of the input keys.
The name of the key pressed will be displayed on the lower line of the screen. However, when the [FEED] key is pressed, the name of the pressed key is not displayed on the screen but the paper feed of printer paper is carried out.

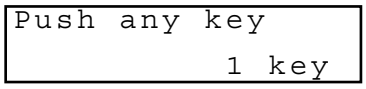

Figure 8-7: Key Entry Test Screen

If you press the [SELECT] key, the display will return to the Test Program Menu screen (Figure 8-2).

4.5 Built-in Printer Test

Print out dummy data and check the performance of the printer.

(1) Press the [4] key on the Test Program Menu screen.
The Built-In Printer Test screen will appear, and a test printout will start.
When the printout is completed, the display will return to the Test Program Menu screen (Figure 8-2).

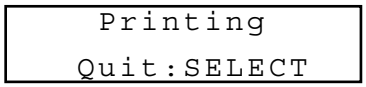

Figure 8-8: Built-In Printer Test Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Test Program Menu screen (Figure 8-2).

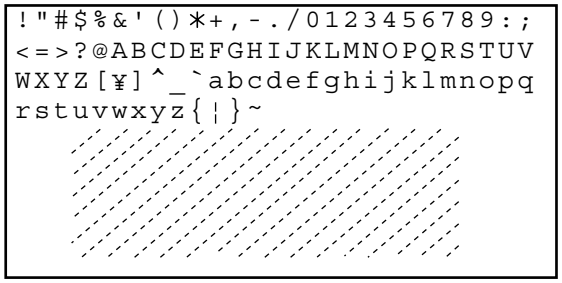

Figure 8-9: Test Printout

(2) Check the printout.

4.6 Communication Test

Test the communication with the host computer.

(1) Press the [5] key on the Test Program Menu screen.
The Communication Test screen will appear.

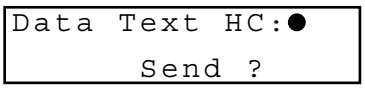

Figure 8-10: Communication Test Screen

CAUTION:
- "●" in Figure 8-10 shows the status of the connection with the host computer (HC).
  ○: The host computer is ready for receiving signals.
  ●: The host computer is not ready for receiving signals.
  In this case, check the power of the host computer and the condition of the connection cable, and make them ready for communication.

If you press the [SELECT] key, the display will return to the Test Program Menu screen (Figure 8-2).

(2) Press the [ENTER] key.
The display will change from "Send?" to "Sending", and test text will be transmitted to the host computer. When the class B is selected, the CA-50 will wait for the response from the host computer.
When the transmission is completed, the display will change from "Sending" to "Send?".
If you press the [SELECT] key, the display will return to the Test Program Menu screen (Figure 8-2).

4.7 LCD Screen Test

Check the LCD screen to see that all the dots are intact.

(1) Press the [6] key on the Test Program Menu screen.
The whole screen will be black for a test.

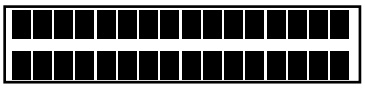

Figure 8-11: LCD Test Screen

(2) Check that all the dots are intact.
If you press the [SELECT] key, the display will return to the Test Program Menu screen (Figure 8-2).

CHAPTER 9 FUNCTIONAL DESCRIPTION

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   - 2.4 Standard Curve for Coagulation Method 9-5
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   - 4.3 Bottom 9-14

1. INTRODUCTION

This chapter explains the coagulation detection principles and analysis flow in the CA-50.

Detection Principles
Explains the detection principles for Coagulation Method.

Analysis Flow
Describes the required sample volume and reagent volume for each analysis parameter.

2. DETECTION PRINCIPLES FOR COAGULATION METHOD

After a fixed quantity of blood plasma has been incubated for a certain time period, reagent is added. The sample to which the reagent has been added is then exposed to light having a wavelength of 660 nm, and the turbidity of the blood during the coagulation process is detected as the change in scattered light intensity.
From this change in scattered light intensity, a coagulation curve is prepared and the coagulation time is found by means of the Percentage Detection Method.

2.1 Optical Detection Method (Scattered Light Detection Method)

The CA-50 utilizes the Optical Detection Method and thus detects the change in turbidity of blood during the coagulation process as the change in scattered light intensity.
Light that is emitted from a light source reaches the sample. The scattered light that is generated is received by a photodiode, which converts the light into electrical signals. These signals are stored and calculated by a microcomputer in order to find the coagulation time.

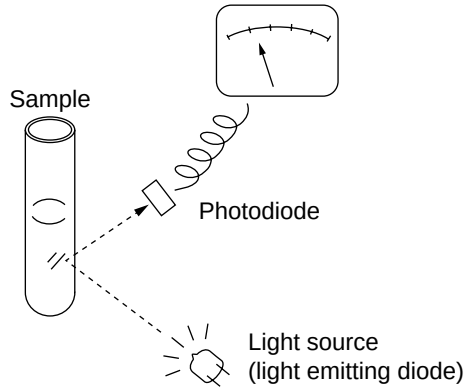

Figure 9-1: Optical Detection System

2.2 Blood Coagulation and Scattered Light Intensity

The relationship between blood coagulation and scattered light is described below.

Step 1: Add incubated reagent to plasma that has also been incubated for a certain time period.

Step 2: Scattered light is weak and there is almost no change in the sample immediately after the reagent is added.

Steps 3 - 4: As the reaction gradually progresses, fibrin clots begin to form. At the same time, the sample becomes cloudy and a sharp increase in scattered light intensity is detected.

Step 5: After coagulation is completed, the increase in scattered light intensity ceases and stabilizes at a certain scattering level.

As described above, the CA-50 can record the blood coagulation process as the change in scattered light intensity and then output the coagulation curve.

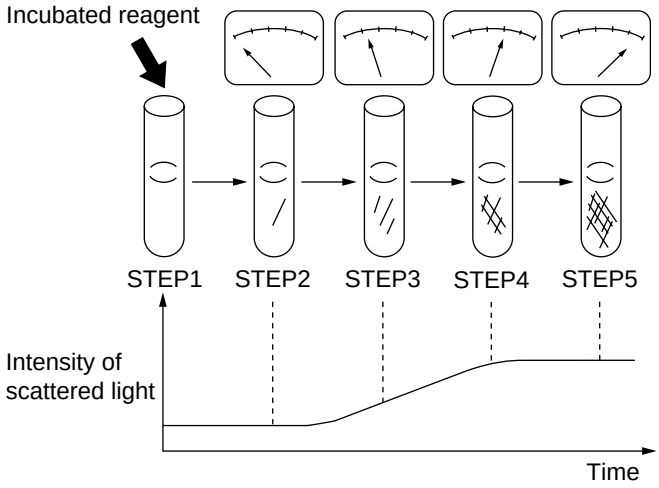

Figure 9-2: Blood Coagulation Time and Intensity of Scattered Light

2.3 Coagulation Point Detection Method (Percentage Detection Method)

To detect the coagulation time, the Percentage Detection Method is employed.
The level of scattered light intensity that is present right after the coagulation reagent is added but before coagulation has started is defined as 0%, and the level of scattered light intensity that is present after coagulation is completed is defined as 100%. The time that it takes for the level of scattered light intensity to reach the preset detection percentage is found from the coagulation curve. This is defined as the coagulation time. (The coagulation detection point is set at 50% in the figure below.) With this method, the coagulation time can be detected if even small changes in scattered light intensity take place.
The coagulation time can thus be detected using samples that show small changes in scattered light intensity (low-fibrinogen samples) or even samples whose speed of change is only slight (samples with extended coagulation time).

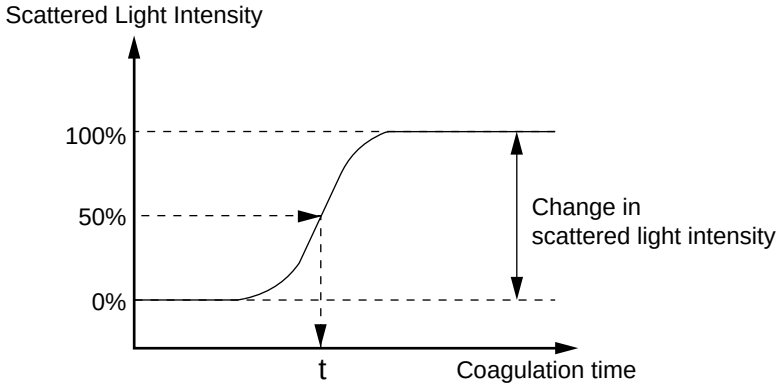

Figure 9-3: Determination of Coagulation Time

2.4 Standard Curve for Coagulation Method

In general with regard to parameters whose coagulation detection principle is the Coagulation Method, a linear relationship exists between the time and activity percent (or concentration) when they are plotted on a log-log graph. The CA-50 can make use of the aforementioned relationship to prepare standard curves. The standard curves are made by joining consecutive pairs of concentrations (or activity percent) with straight lines. The two ends of the standard curves are made by extending the line made between the pair of concentration points (or activity percent) that are nearest the end.

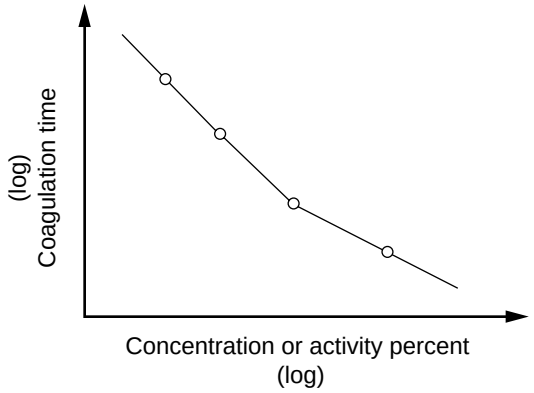

Figure 9-4: Standard Curve for Coagulation Method

By changing the settings, you can also select the following standard curve format:
(1) Log-log linear approximation
(2) Log-log polygonal line
(3) Real number-real number linear approximation

2.5 Calculation of PT Ratio and INR Value

The CA-50 can calculate a PT ratio and display it, if the normal PT value has been entered in the Standard Curve program. The International Normalized Ratio (INR) will be displayed and printed with analysis results if the International Sensitivity Index (ISI) of the PT reagent has also been entered in the Standard Curve program.

$$\text{PT ratio} = \frac{\text{PT coagulation time of sample plasma}}{\text{Normal PT value}}$$

$$\text{INR} = (\text{PT ratio})^{\text{ISI}}$$

2.6 Analysis Flow

CAUTION • Follow the analysis flows shown below when performing the analyses. If the flow is not appropriate, the correct result cannot be obtained.
• When sample's dilution magnification is changed, it is necessary to convert the analysis result. (High Fbg concentration, etc.)

- **PT Flow**

Sample Volume	Plasma	50 μL
Reagent Volume	PT reagent	100 μL

Table 9-1: Sample/Reagent Volume - PT

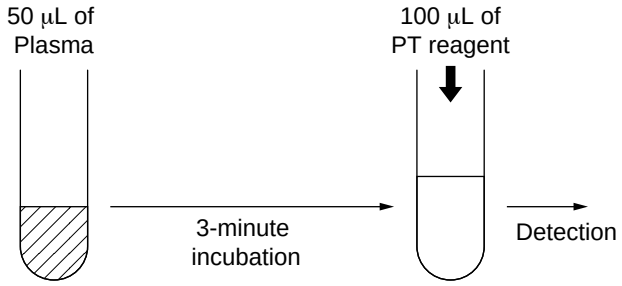

Figure 9-5: PT Flow

- **APTT Flow**

Sample Volume	Plasma	50 μL
Reagent Volume	APTT reagent	50 μL
	Calcium Chloride Solution	50 μL

Table 9-2: Sample/Reagent Volume - APTT

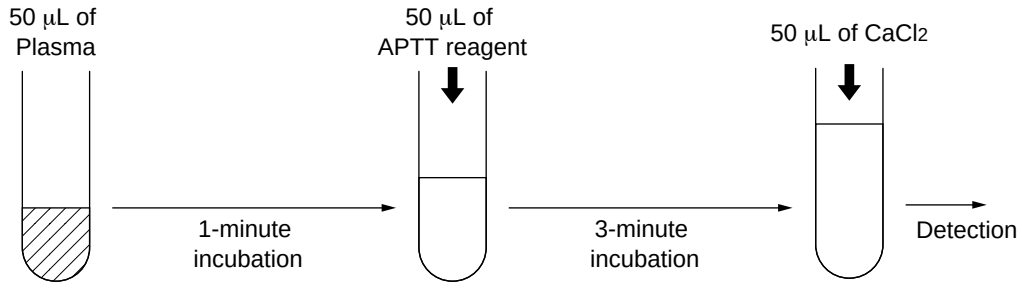

Figure 9-6: APTT Flow

- **Fbg Flow**

Sample Volume	Plasma	10 µL
Reagent Volume	Thrombin reagent	50 µL
	Owren's Veronal buffer	90 µL

Table 9-3: Sample/Reagent Volume - Fbg

* Samples with high Fbg concentration are prepared with 5 µL of plasma and 95 µL of buffer for analysis.
Samples with low Fbg concentration are prepared with dilution ratio of 1/5 (20 µL of plasma with 80 µL of buffer) for analysis.
In this case, it is necessary to convert the analysis result.

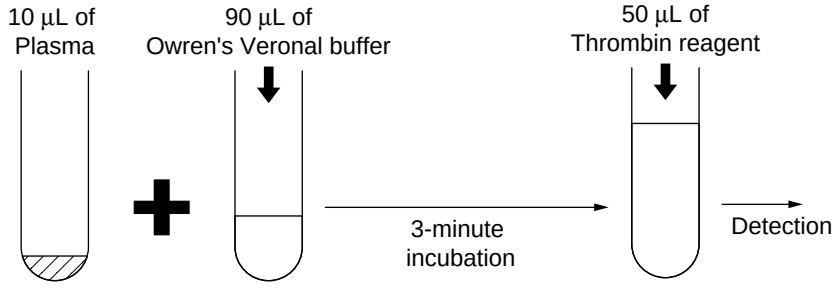

Figure 9-7: Fbg Flow

- **TTO Flow**

Sample Volume	Plasma	20 µL
Reagent Volume	TTO reagent	125 µL
	Owren's Veronal buffer	30 µL

Table 9-4: Sample/Reagent Volume - TTO

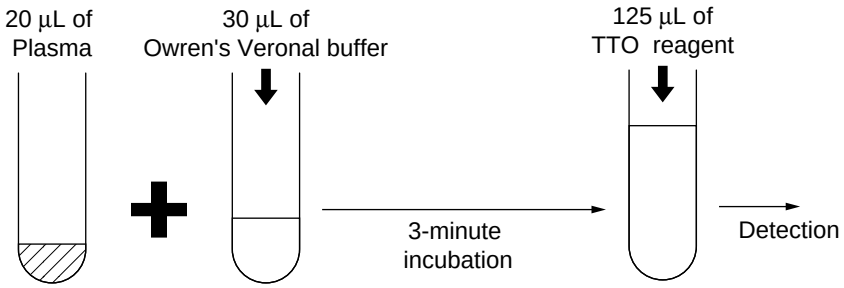

Figure 9-8: TTO Flow

- **NT Flow**

Sample Volume	Plasma	10 µL
Reagent Volume	NT reagent	125 µL
	Owren's Veronal buffer	40 µL

Table 9-5: Sample/Reagent Volume - NT

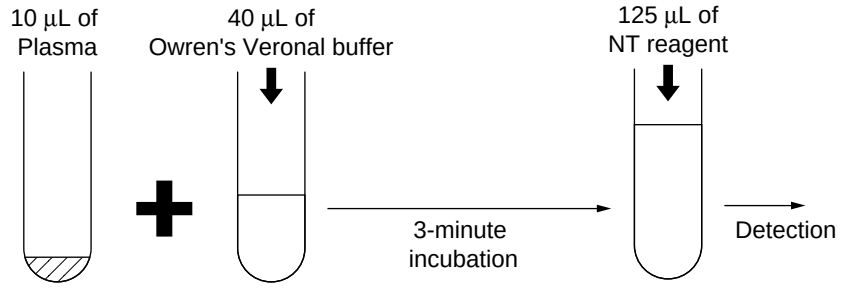

Figure 9-9: NT Flow

- **TT Flow**

Sample Volume	Plasma	100 µL
Reagent Volume	Thrombin Time reagent	50 µL

Table 9-6: Sample/Reagent Volume - TT

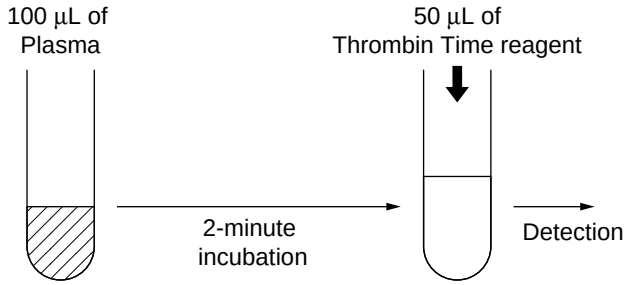

Figure 9-10: TT Flow

- **Extrinsic Factor Analysis Flow**

Sample Volume	Plasma	5 μL
Reagent Volume	PT reagent	100 μL
	Owren's Veronal buffer	45 μL
	Factor-deficient plasma	50 μL

Table 9-7: Sample/Reagent Volume - Extrinsic Factor

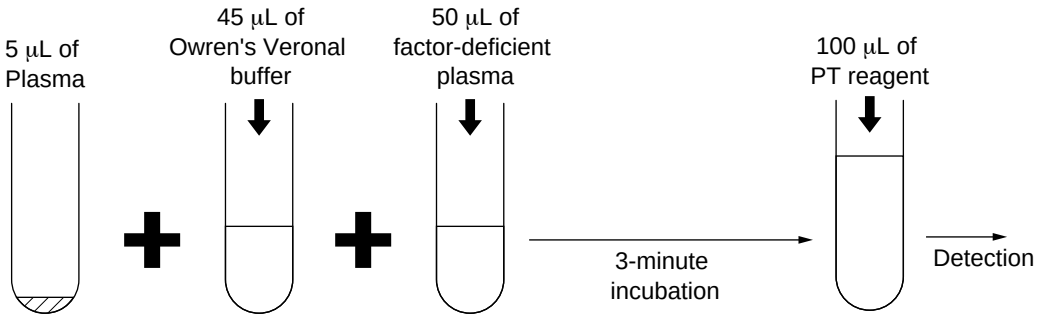

Figure 9-11: Extrinsic Factor Analysis Flow

- **Intrinsic Factor Analysis Flow**

Sample Volume	Plasma	5 μL
Reagent Volume	APTT reagent	50 μL
	Calcium Chloride Solution	50 μL
	Owren's Veronal buffer	45 μL
	Factor-deficient plasma	50 μL

Table 9-8: Sample/Reagent Volume - Intrinsic Factor

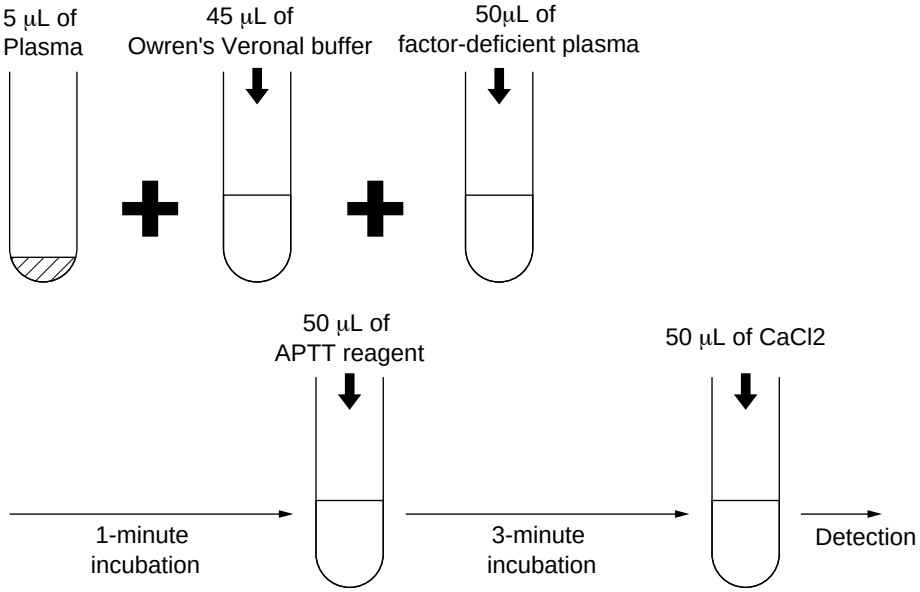

Figure 9-12: Intrinsic Factor Analysis Flow

3. ANALYSIS MECHANISM

The CA-50 employs units of the mechanical and electrical systems, and performs analysis according to the procedure described below.

1. The incubator warms (incubates) the reagent.

2. The sample-containing reaction tubes are warmed (incubated).

3. When the reagent is added, the addition is detected automatically, and the sample is agitated. Then detection of analysis starts.

4. In the detector block, coagulation reaction is detected through the change in scattered light.

4. INSTRUMENT COMPONENTS AND FUNCTIONS

4.1 Front, Top, and Right Side

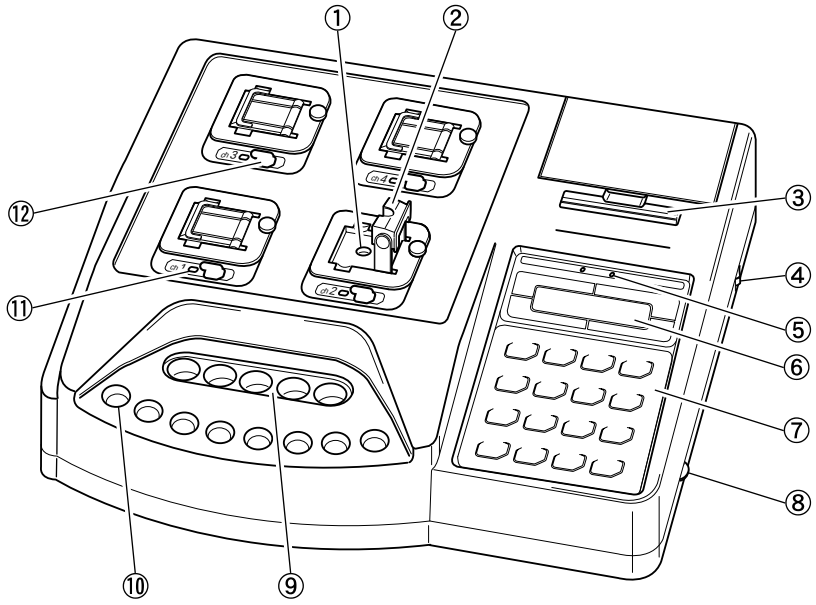

Figure 9-13: Front, Top, and Right Side View

(1) Detector
Analyzes samples.

(2) Pipette guide
Used to hold the pipette chip when reagent is added and to cover the detector.

> **WARNING** • Do not open the pipette guide during analysis and put your fingers or the like into it. Otherwise, you may get injured.
> When the pipette guide is opened during analysis, the alarm sounds, then the analysis stops.

(3) Built-in printer
Prints analysis results and setting contents.

(4) Power switch
Turns the power ON/OFF.

> **CAUTION** • Do not turn the power switch ON/OFF repeatedly in a short interval. If you do, it can cause the damage to the unit.

(5) measure mode LED
Indicates the measure modes (single measure mode [SINGLE], replication measure mode [DOUBLE]).

(6) LCD screen
Displays analysis conditions, analysis results, and error messages.

(7) Input key
Used to perform the operation and settings in the CA-50.

(8) LCD brightness control knob
Turn this knob to adjust the brightness on the LCD screen.

(9) Incubator
Warms (Incubates) the reagent in the sample cup.

(10) Reaction tube holder
Used to set reaction tubes. Temperature control is not performed.

(11) Detector LED
Indicates the timing to add reagents and the instrument's status.

(12) Analysis start switch
Press this button to analyze samples.

4.2 Rear

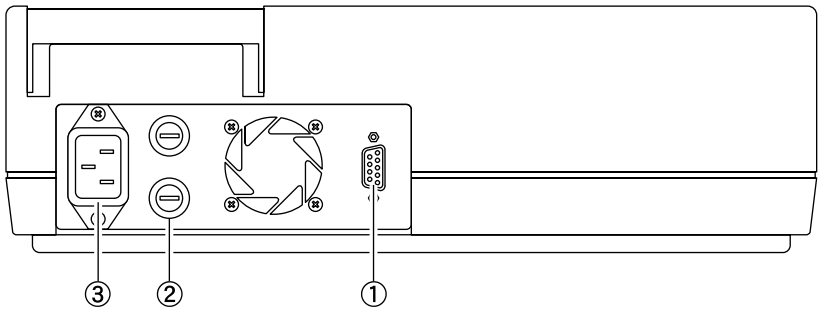

Figure 9-14: Rear View

(1) Connector
Used to connect the host computer.

(2) Fuse
Two time-lag-type fuses are installed in this fuse holder. The rating will be different depending on the instrument specification as below.

Specification	Part No.	Description	Type
117VAC	266-5110-5	Fuse 250V1A ST-4-0.8A-N1 (N.Amer)	Time Lag
220/240VAC	266-7132-4	Fuse S504 T0.4A-T	Time Lag

WARNING • To avoid risk of electrical shock, disconnect the power cord before replacing the fuses.

CAUTION • For continued protection against risk of fire, replace only with a fuse of the specified type and ratings.

(3) Power connector
Connects the provided power cord to supply power.

4.3 Bottom

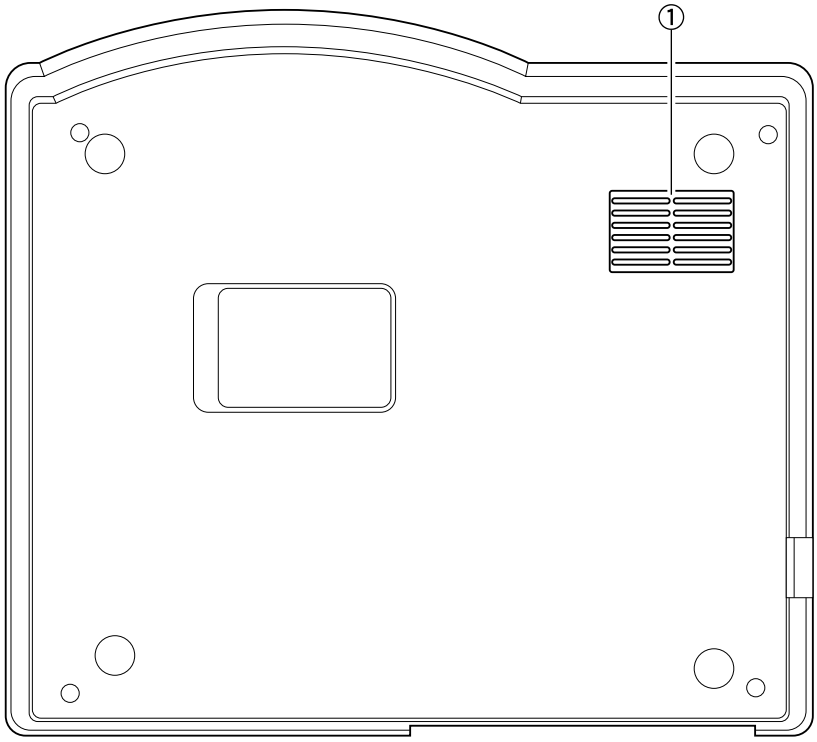

Figure 9-15: Bottom View

(1) Filter (Filter Media)
Prevents dust from entering the instrument.

CHAPTER 10 INSTRUMENT SETUP

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1. INTRODUCTION

System setup of the CA-50 will be performed by your Sysmex Service Representative when the instrument is installed. However, the settings can be changed by using this program.
This chapter explains how to use this setting program.

Measure Settings
Can preset the upper and lower limits for checking analysis results. Can also preset test protocols, measure modes, and other settings relating to analysis.

I/O Settings
Can preset the interface conditions for the host computer connected to the CA-50, and printout conditions for the built-in printer.

System Settings
Can preset parameters relating to the overall CA-50 system.

2. SETTING MENU

(1) Press the [SELECT] key to enter the Main Menu screen.

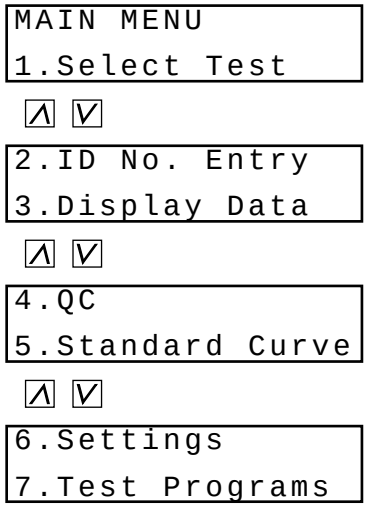


Figure 10-1: Main Menu Screen

(2) Press the [6] key on the Main Menu screen. The Setting Menu screen will appear. You can scroll the menu up and down by using the [Λ] and [V] keys.

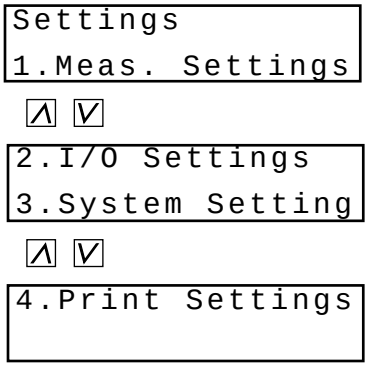


Figure 10-2: Setting Menu Screen

Pressing the following key will select each menu function.

[1] key: Displays the measure setting menu (Meas. Settings).
[2] key: Displays the I/O setting menu (I/O Settings).
[3] key: Displays the system setting menu (System Setting).
[4] key: Prints out the contents of all the settings (Print Settings).
[PRINT]key : Prints out the setting menu.
[SELECT] key: Returns the screen to the main menu.

3. MEASURE SETTINGS

3.1 Measure Setting Menu

When you press the [1] key on the Setting Menu screen, the Measure Setting Menu screen will appear.
You can scroll the menu up and down by using the [Λ] and [V] keys.

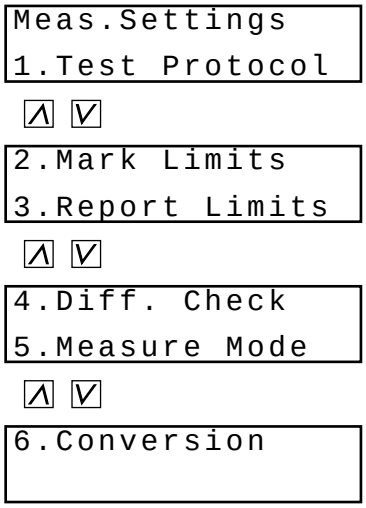


Figure 10-3: Measure Setting Menu Screen

Pressing the following key will select each menu function.

[1] key:	Displays the test protocol setting menu (Test Protocol).
[2] key:	Displays the mark limit setting menu (Mark Limits).
[3] key:	Displays the report limit setting menu (Report Limits).
[4] key:	Displays the replication difference limit setting menu (Diff. Check).
[5] key:	Moves the screen to the measure mode & sample incubation ready check settings (Measure Mode).
[6] key:	Displays the conversion setting menu (Conversion).
[PRINT] key:	Prints out the measure setting menu.
[SELECT] key:	Returns the screen to the setting menu.

3.2 Test Protocol Settings

Set the test protocol (analysis procedure) for each analysis parameter.

> **CAUTION** • If you change the test protocol (excluding the maximum detection time), correct analysis results may not be obtained. The change must be made on your own responsibility.

1. Test Protocol Setting Menu

When you press the [1] key on the Measure Setting Menu screen, the Test Protocol Setting Menu screen will appear.
You can scroll the menu up and down by using the [Λ] and [V] keys.

```
Test Protocol
1.Select Test
```

[Λ] [V]

```
2.Input
3.Print
```

Figure 10-4: Test Protocol Setting Menu Screen

Pressing the following key will select each menu function.
[1] key: Moves the screen to the selection of analysis parameters (Select Test).
[2] key: Moves the screen to the test protocol setting (Input).
[3] key: Prints out the contents of the test protocol settings (Print).
[PRINT] key: Prints out the test protocol setting menu.
[SELECT] key: Returns the screen to the measure setting menu.

2. Selecting Analysis Parameter

Select the analysis parameter for which you wish to set the test protocol.

(1) Press the [1] key on the Test Protocol Setting Menu screen.
The Analysis Parameter Selection screen will appear.

```
Test Protocol
Test(PT-EX)? PT
```

Figure 10-5: Analysis Parameter Selection Screen

If you press the [SELECT] key, the display will return to the Test Protocol Setting Menu screen (Figure 10-4).

(2) Press the key for the desired parameter and press the [ENTER] key.
The display will return to the Test Protocol Setting Menu screen (Figure 10-4).

3. Setting Test Protocol

Set a coagulation detection point (see *Chapter 9, Section 2.3: Coagulation Point Detection Method (Percentage Detection Method*), maximum detection time, and reagent addition allowed time (start and end).
See *APPENDIX B, Section 2.4: Instrument Setting Parameters and Factory Default Settings* for the settings of factory default.

NOTE: • For the intrinsic factor (IN) and the extrinsic factor (EX), only one test protocol can be set for each.

(1) Press the [2] key on the Test Protocol Setting Menu screen.
The Coagulation Detection Point Entry screen will appear.

```
Protocol    PT
% End Point? 50%
```

Figure 10-6: Coagulation Detection Point Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-13) will appear.

(2) Input a coagulation detection point and press the [ENTER] key.
You can input the value in the range of 2 to 80 %.
If you do not change the value, press the [ENTER] key only.
The Maximum Detection Time Entry screen will appear.

```
Protocol    PT
Max time? 100sec
```

Figure 10-7: Maximum Detection Time Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-13) will appear.

(3) Input maximum detection time and press the [ENTER] key.
You can input the value in the range of 100 to 600 seconds for PT and Fbg, and 190 to 600 seconds for the other parameters.
If you do not change the value, press the [ENTER] key only.
The Sensitivity Selection screen will appear.

```
Protocol    PT
Sense?      Low
```

Figure 10-8: Sensitivity Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-13) will appear.

(4) Select the desired sensitivity by using the [∧] and [∨] keys, and press the [ENTER] key. The display will be switched in the order of "High" and "Low" each time the [∧] or [∨] key is pressed.
The First Reagent Addition Timing Entry screen will appear.

```
Protocol     PT
Reag1?     180sec
```

Figure 10-9: First Reagent Addition Timing Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-13) will appear.

(5) Input the timing of adding the first reagent within the range of 0 to 999, and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The Allowed Time Starting Point Entry screen will appear.

```
Protocol     PT
Before?      5sec
```

Figure 10-10: Allowed Time Starting Point Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-13) will appear.

(6) Input how many seconds before the addition timing the allowed time should start within the range of 0 to 99, and press the [ENTER] key. See *Chapter 3, Section 3.2: Adding the Reagents* for the reagent addition allowed time.
If you do not change the value, press the [ENTER] key only.
The Allowed Time End Point Entry screen will appear.

```
Protocol     PT
After?       5sec
```

Figure 10-11: Allowed Time End Point Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-13) will appear.

(7) Input how many seconds after the addition timing the allowed time should end within the range of 0 to 99, and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The Second Reagent Addition Timing Entry screen will appear.

```
Protocol     PT
Reag2?       0sec
```

Figure 10-12: Second Reagent Addition Timing Entry Screen

(8) Input the timing of adding the second reagent within the range of 0 to 999, and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
When the second reagent is not required, check that the addition timing is displayed as "0". If any number except "0" is displayed, input "0" and press the [ENTER] key.
The Allowed Time Starting Point Entry screen will appear.

(9) Input the reagent addition allowance time (Start) and (End) of the second reagent as well as above-mentioned (6) and (7).

(10) Press the [SELECT] key.
The Update Confirmation screen will appear.

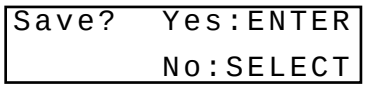


Figure 10-13: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Test Protocol Setting Menu screen (Figure 10-4).

(11) Press the [ENTER] key.
The settings will be updated and the display will return to the Test Protocol Setting Menu screen (Figure 10-4).

4. Printing Out Test Protocol Settings

Print out the contents of the test protocol settings.

(1) Press the [3] key on the Test Protocol Setting Menu screen.
The Printing screen will appear and the printout of the test protocol settings will start. When the printout is completed, the display will return to the Test Protocol Setting Menu screen (Figure 10-4).

```
Printing
Quit:SELECT
```

Figure 10-14: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Test Protocol Setting Menu screen (Figure 10-4).

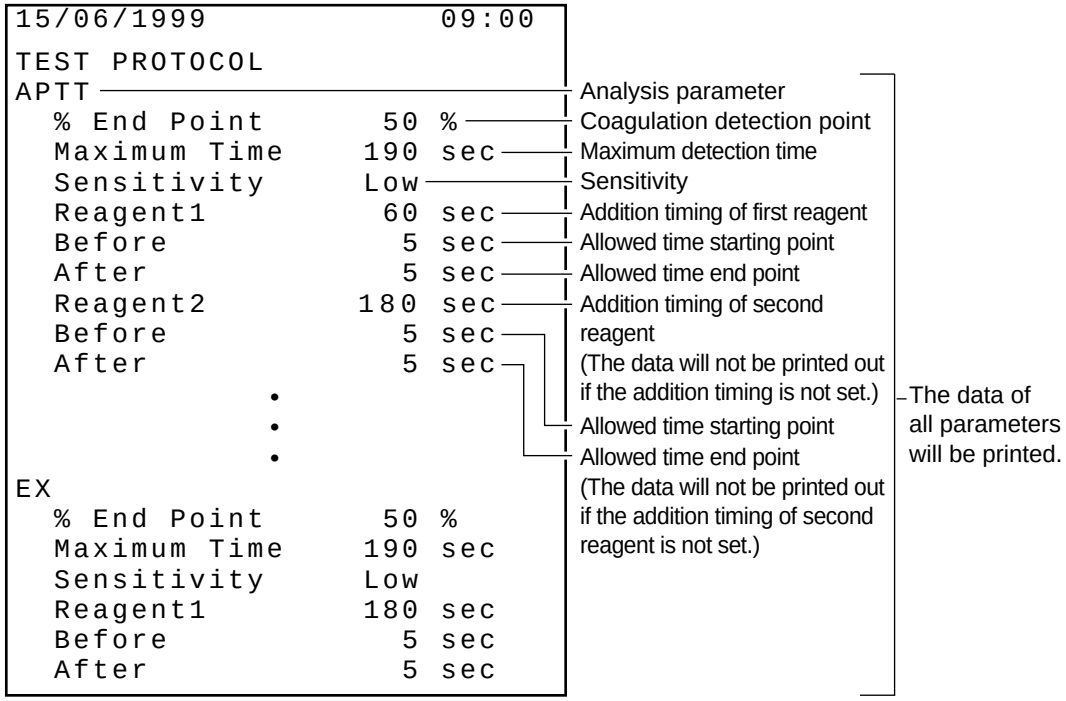

15/06/1999 09:00
TEST PROTOCOL
APTT
% End Point 50 %
Maximum Time 190 sec
Sensitivity Low
Reagent1 60 sec
Before 5 sec
After 5 sec
Reagent2 180 sec
Before 5 sec
After 5 sec
EX
% End Point 50 %
Maximum Time 190 sec
Sensitivity Low
Reagent1 180 sec
Before 5 sec
After 5 sec
Analysis parameter
Coagulation detection point
Maximum detection time
Sensitivity
Addition timing of first reagent
Allowed time starting point
Allowed time end point
Addition timing of second reagent
(The data will not be printed out if the addition timing is not set.)
Allowed time starting point
Allowed time end point
(The data will not be printed out if the addition timing of second reagent is not set.)
The data of all parameters will be printed.

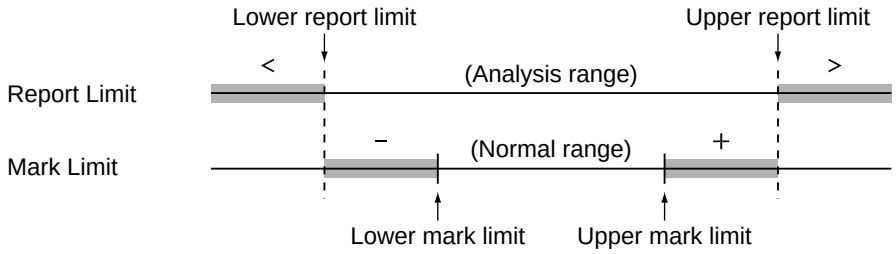
Figure 10-15: Printout Example of Test Protocol Settings

3.3 Data Check Parameter & Mark Limit Settings

Set the upper and lower limits to check for abnormal analysis results.
If analysis results exceed the preset normal range, either of the following mark limit flags will appear with the analysis results:

- +: Analysis results exceeded the upper mark limit.
- - : Analysis results exceeded the lower mark limit.

NOTE:



- The above figure shows the relation between the mark limits and the report limits to be set in *Section 3.4 Report Limit Settings*. Note that the above relation holds when the lower mark limit is smaller than the upper mark limit. For mark limits, it is possible that you set a smaller value (e.g. shorter time) as the upper limit and a larger value (e.g. longer time) as the lower limit. In this case, "+" will appear when the analysis results are smaller than the upper limit, and "-" will appear when the analysis results are greater than the lower limit.

1. Mark Limit Setting Menu

When you press the [2] key on the Measure Setting Menu screen, the Mark Limit Setting Menu screen will appear.
You can scroll the menu up and down by using the [Λ] and [V] keys.

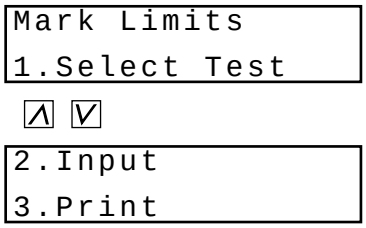


Figure 10-16: Mark Limit Setting Menu Screen

Pressing the following key will select each menu function.
[1] key: Moves the screen to the selection of analysis parameters (Select Test).
[2] key: Moves the screen to the data check parameter and mark limit settings (Input).
[3] key: Prints out the contents of the mark limit settings (Print).
[PRINT] key: Prints out the mark limit setting menu.
[SELECT] key: Returns the screen to the measure setting menu.

2. Selecting Analysis Parameter

Select the analysis parameter for which you wish to set the mark limits.

(1) Press the [1] key on the Mark Limit Setting Menu screen.
The Analysis Parameter Selection screen will appear.

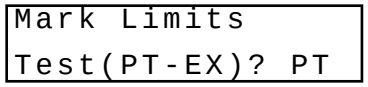


Figure 10-17: Analysis Parameter Selection Screen

If you press the [SELECT] key, the display will return to the Mark Limit Setting Menu screen (Figure 10-16).

(2) Press the key for the desired parameter and press the [ENTER] key.
In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key.
In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key.
If you press the [IN] or [EX] key, the Factor Number Entry screen will appear.
When you press any of the other keys, the display will return to the Mark Limit Setting Menu screen (Figure 10-16).

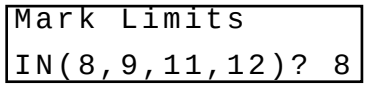


Figure 10-18: Factor Number Entry Screen

If you press the [SELECT] key, the display will return to the Analysis Parameter Selection screen (Figure 10-17).

(3) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12.
In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10.
Then press the [ENTER] key.
The display will return to the Mark Limit Setting Menu screen (Figure 10-16).

3. Setting Data Check Parameter and Mark Limits

Set the upper and lower limits to check for abnormal analysis results. Also, for each analysis parameter, select time or any of calculation parameters as a data check parameter to be used in checking analysis results.
When you set 0 or the same value for both of the upper and lower limits, data check against mark limits will not be performed.
The data check parameter set here will work as a data check parameter for report limits.

(1) Press the [2] key on the Mark Limit Setting Menu screen.
The Data Check Parameter Selection screen will appear.

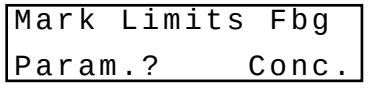


Figure 10-19: Data Check Parameter Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-22) will appear.

(2) Select the desired data check parameter by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched in the order of "analysis parameter" (coagulation time), "Act." ("Conc." in the case of Fbg), "Ratio", "INR", and "DFbg" each time the [∨] key is pressed. Note that only the parameters that have been selected as the calculation parameters for standard curves will be displayed.
The Lower Limit Entry screen will appear.

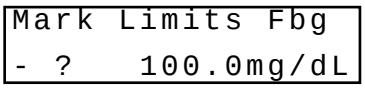


Figure 10-20: Lower Limit Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-22) will appear.

(3) Input a lower limit and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The Upper Limit Entry screen will appear.

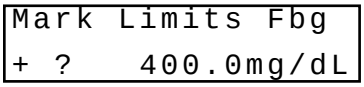


Figure 10-21: Upper Limit Entry Screen

If you press the [ENTER] key, the display will return to the Data Check Parameter Selection screen (Figure 10-19).

(4) Input an upper limit and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.

(5) Press the [SELECT] key.
The Update Confirmation screen will appear.

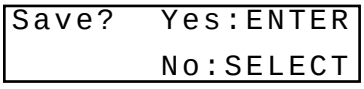


Figure 10-22: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Mark Limit Setting Menu screen (Figure 10-16).

(6) Press the [ENTER] key.
The settings will be updated and the display will return to the Mark Limit Setting Menu screen (Figure 10-16).
Update is possible even when the inputted upper limit is smaller than the lower limit. However, in this case, "+" will appear with analysis results when the analysis results are smaller than the upper limit, and "-" will appear when the analysis results are greater than the lower limit.

4. Printing Out Mark Limit Settings

Print out the contents of the mark limit settings.

(1) Press the [3] key on the Mark Limit Setting Menu screen.
The Printing screen will appear and the printout of the mark limit settings will start. When the printout is completed, the display will return to the Mark Limit Setting Menu screen (Figure 10-16).

```
Printing
Quit:SELECT
```

Figure 10-23: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Mark Limit Setting Menu screen (Figure 10-16).

```
15/06/1999                09:00

CHECK PARAMETER
PT          Act.      %
APTT        APTT      sec
Fbg         Conc.     mg/dL
TTO         Act.      %
NT          Act.      %
TT          TT        sec
F8          Act.      %
F9          Act.      %
F11         Act.      %
F12         Act.      %
F2          Act.      %
F5          Act.      %
F7          Act.      %
F10         Act.      %

MARK LIMITS
                -         +
PT            0.0       0.0 %
APTT          0.0       0.0 sec
Fbg           0.0       0.0 mg/dL
TTO           0.0       0.0 %
NT            0.0       0.0 %
TT            0.0       0.0 sec
F8            0.0       0.0 %
F9            0.0       0.0 %
F11           0.0       0.0 %
F12           0.0       0.0 %
F2            0.0       0.0 %
F5            0.0       0.0 %
F7            0.0       0.0 %
F10           0.0       0.0 %
```

Data check parameters for 14 analysis parameters

Mark limits for 14 analysis parameters

Figure 10-24: Printout Example of Mark Limit Settings

3.4 Report Limit Settings

Set the upper and lower report limits to check for abnormal analysis results out of the preset analysis range.
If analysis results exceed the preset report limit range, the analysis results will be shown as follows:

- >: Upper limit: Analysis results exceeded the upper report limit.
- <: Lower limit: Analysis results exceeded the lower report limit.

For example, when the upper limit is set at 450 and analysis results exceed 450, the analysis results will be displayed as ">450". When the lower limit is set at 50 and analysis results are below 50, the analysis results will be displayed as "<50".

The data check parameter for report limits will be the same as that for mark limits. For details, see *Section 3.3: Data Check Parameter & Mark Limit Settings*

NOTE:	• Report limits have precedence over mark limits.

1. Report Limit Setting Menu

When you press the [3] key on the Measure Setting Menu screen, the Report Limit Setting Menu screen will appear.
You can scroll the menu up and down by using the [Λ] and [V] keys.

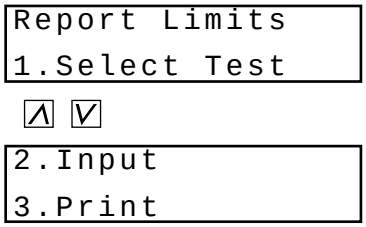


Figure 10-25: Report Limit Setting Menu Screen

Pressing the following key will select each menu function.
[1] key: Moves the screen to the selection of analysis parameters (Select Test).
[2] key: Moves the screen to the report limit setting (Input).
[3] key: Prints out the contents of the report limit settings (Print).
[PRINT] key: Prints out the report limit setting menu.
[SELECT] key: Returns the screen to the measure setting menu.

2. Selecting Analysis Parameter

Select the analysis parameter for which you wish to set the report limits.

(1) Press the [1] key on the Report Limit Setting Menu screen.
The Analysis Parameter Selection screen will appear.

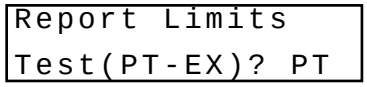


Figure 10-26: Analysis Parameter Selection Screen

If you press the [SELECT] key, the display will return to the Report Limit Setting Menu screen (Figure 10-25).

(2) Press the key for the desired parameter and press the [ENTER] key.
In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key.
In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key.
If you press the [IN] or [EX] key, the Factor Number Entry screen will appear.
When you press any of the other keys, the display will return to the Report Limit Setting Menu screen (Figure 10-25).

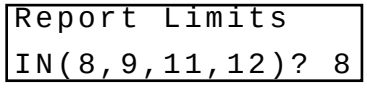


Figure 10-27: Factor Number Entry Screen

If you press the [SELECT] key, the display will return to the Analysis Parameter Selection screen (Figure 10-26).

(3) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12.
In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10.
Then press the [ENTER] key.
The display will return to the Report Limit Setting Menu screen (Figure 10-25).

3. Setting Report Limits

Set the upper and lower limits to check for abnormal analysis results out of the analysis range. When you set 0 or the same value for both of the upper and lower limits, data check against report limits will not be performed.

(1) Press the [2] key on the Report Limit Setting Menu screen.
The Lower Limit Entry screen will appear.

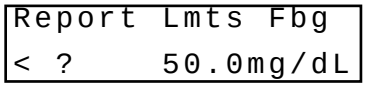


Figure 10-28: Lower Limit Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-30) will appear.

(2) Input a lower limit and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The Upper Limit Entry screen will appear.

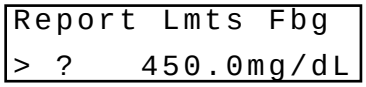


Figure 10-29: Upper Limit Entry Screen

If you press the [ENTER] key, the display will return to the Lower Limit Entry screen (Figure 10-28).

(3) Input an upper limit and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.

(4) Press the [SELECT] key.
The Update Confirmation screen will appear.

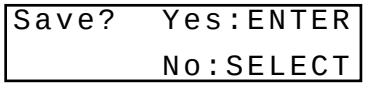


Figure 10-30: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Report Limit Setting Menu screen (Figure 10-25).

(5) Press the [ENTER] key.
The settings will be updated and the display will return to the Report Limit Setting Menu screen (Figure 10-25).
When the inputted upper limit is smaller than the lower limit, a setting error will occur and the Lower Limit Entry screen (Figure 10-28) will appear. Go back to step (2) and reenter report limits.

4. Printing Out Report Limit Settings

Print out the contents of the report limit settings.

(1) Press the [3] key on the Report Limit Setting Menu screen.
The Printing screen will appear and the printout of the report limit settings will start. When the printout is completed, the display will return to the Report Limit Setting Menu screen (Figure 10-25).

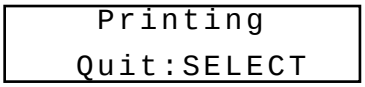
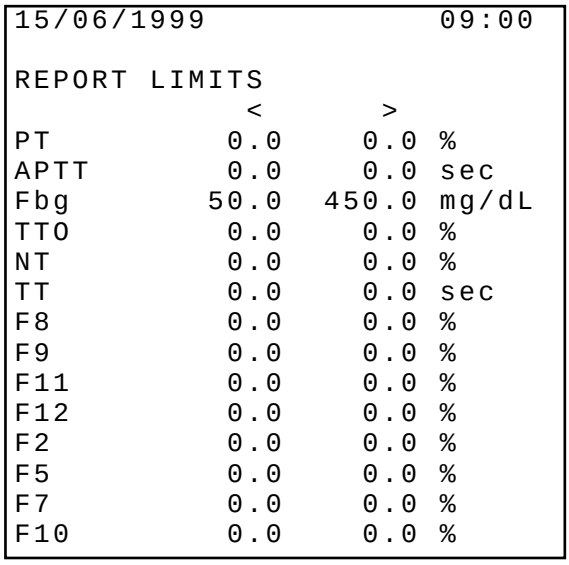


Figure 10-31: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Report Limit Setting Menu screen (Figure 10-25).



15/06/1999 09:00

REPORT LIMITS

	<	>	
PT	0.0	0.0	%
APTT	0.0	0.0	sec
Fbg	50.0	450.0	mg/dL
TTO	0.0	0.0	%
NT	0.0	0.0	%
TT	0.0	0.0	sec
F8	0.0	0.0	%
F9	0.0	0.0	%
F11	0.0	0.0	%
F12	0.0	0.0	%
F2	0.0	0.0	%
F5	0.0	0.0	%
F7	0.0	0.0	%
F10	0.0	0.0	%

Figure 10-32: Printout Example of Report Limit Settings

3.5 Replication Difference Limit Settings

Set the replication difference limit to check for disparate analysis results when the replication measure mode is selected. When the single measure mode is selected, the limit set here will be disabled.
If the difference between the respective replication analysis results and their mean data exceeds the preset replication difference limit, "*" will appear on the left of the mean data.

1. Replication Difference Limit Setting Menu

When you press the [4] key on the Measure Setting Menu screen, the Replication Difference Limit Setting Menu screen will appear.
You can scroll the menu up and down by using the [Λ] and [V] keys.

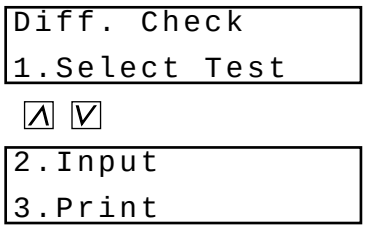


Figure 10-33: Replication Difference Limit Setting Menu Screen

Pressing the following key will select each menu function.
[1] key: Moves the screen to the selection of analysis parameters (Select Test).
[2] key: Moves the screen to the setting of a replication difference limit (Input).
[3] key: Prints out the contents of the replication difference limit settings (Print).
[PRINT] key: Prints out the replication difference limit setting menu.
[SELECT] key: Returns the screen to the measure setting menu.

2. Selecting Analysis Parameter

Select the analysis parameter for which you wish to set the replication difference limit.

(1) Press the [1] key on the Replication Difference Limit Setting Menu screen.
The Analysis Parameter Selection screen will appear.

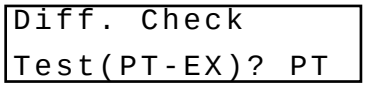


Figure 10-34: Analysis Parameter Selection Screen

If you press the [SELECT] key, the display will return to the Replication Difference Limit Setting Menu screen (Figure 10-33).

(2) Press the key for the desired parameter and press the [ENTER] key.
In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key.
In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key.
If you press the [IN] or [EX] key, the Factor Number Entry screen will appear.
When you press any of the other keys, the display will return to the Replication Difference Limit Setting Menu screen (Figure 10-33).

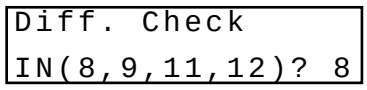


Figure 10-35: Factor Number Entry Screen

If you press the [SELECT] key, the display will return to the Analysis Parameter Selection screen (Figure 10-34).

(3) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12.
In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10.
Then press the [ENTER] key.
The display will return to the Replication Difference Limit Setting Menu screen (Figure 10-33).

3. Setting Replication Difference Limit

Set the replication difference limit. When the limit is set at 0, data check against a replication difference limit will not be performed. And, the replication difference limit is judged by the analysis results of second count.

(1) Press the [2] key on the Replication Difference Limit Setting Menu screen.
The Difference Limit Entry screen will appear.

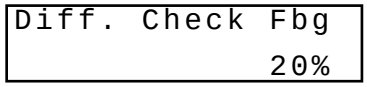


Figure 10-36: Difference Limit Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-37) will appear.

(2) Input a replication difference limit and press the [ENTER] key.
The difference limit to determine a replication analysis error must be based on the following formula:

$$\text{Difference Limit} = \frac{\left|(\text{Result of first or second analysis (second count)} - \text{Mean data (second count)})\right|}{(\text{Mean data (second count)})} \times 100\ (\%)$$

If you do not change the value, press the [ENTER] key only.
The Update Confirmation screen will appear.

```
Save?   Yes:ENTER
        No:SELECT
```

Figure 10-37: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Replication Difference Limit Setting Menu screen (Figure 10-33).

(3) Press the [ENTER] key.
The settings will be updated and the display will return to the Replication Difference Limit Setting Menu screen (Figure 10-33).

4. Printing Out Replication Difference Limit Settings

Print out the contents of the replication difference limit settings.

(1) Press the [3] key on the Replication Difference Limit Setting Menu screen.
The Printing screen will appear and the printout of the replication difference limit settings will start. When the printout is completed, the display will return to the Replication Difference Limit Setting Menu screen (Figure 10-33).

```
    Printing
  Quit:SELECT
```

Figure 10-38: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Replication Difference Limit Setting Menu screen (Figure 10-33).

```
15/06/1999              09:00

DIFFERENCE CHECK        (%)
PT                      20
APTT                    20
Fbg                     20
TTO                     20
NT                      20
TT                      20
F8                      20
F9                      20
F11                     20
F12                     20
F2                      20
F5                      20
F7                      20
F10                     20
```

Figure 10-39: Printout Example of Replication Difference Limit Settings

3.6 Measure Mode & Sample Incubation Ready Check Settings

Select either the single measure mode or the replication measure mode.
Also, it is possible to set the sample incubation ready check, which prevents an analysis from being started when the timings of reagent addition are expected to overlap one another.

Single Measure Mode
An analysis parameter and an ID number can be registered independently on each channel.
When one channel completes an analysis, it is possible to register the next sample and start an analysis even if the other channels are still in process.

Replication Measure Mode
Perform analyses using two channels and calculate mean data from the data obtained by two channels.
Channel 1 and 2, or channel 3 and 4 will be a pair. If you register an analysis parameter and an ID number on channel 1 or 3, the same settings will be applied to channel 2 or 4. The registration and analysis of the next sample cannot be started until both channels used in a pair complete the analysis.

Sample Incubation Ready Check
It is possible to set so as to prevent an analysis from being started when the timings of reagent addition are expected to overlap one another. In that case, the detector LED will turn off and an analysis will not start even if the [Start] switch is pressed.
For example, as shown in Figure 10-40, when you try to analyze PT on multiple channels, the analysis on the second channel cannot be started for 20 seconds from the start of analysis on the first channel so as to avoid the overlap of reagent addition timings. The time in which the start of analysis is disabled is called waiting time. The waiting time when the same analysis parameter is analyzed on multiple channels will be the sum of the time allowed for reagent addition and reagent preparation time. The waiting time when different analysis parameters are analyzed simultaneously will vary depending on the condition of the overlap of reagent addition timings. If you change the allowed time and/or the reagent preparation time, the waiting time will change accordingly.

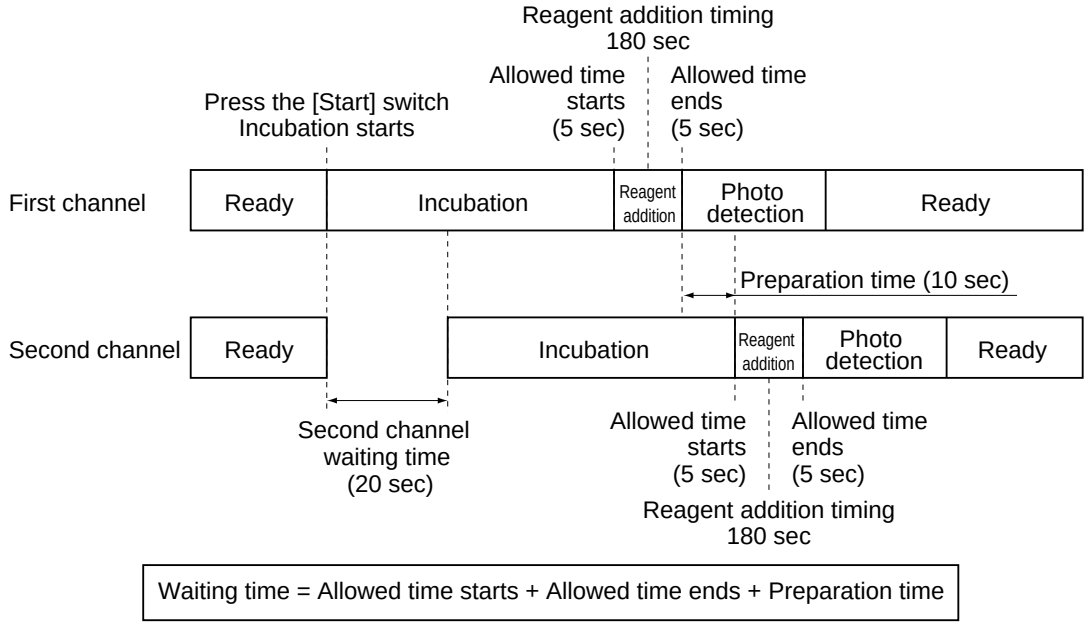


Figure 10-40: Ready Check Mode

(1) Press the [5] key on the Measure Setting Menu screen.
The Measure Mode Setting screen will appear.

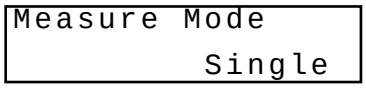


Figure 10-41: Measure Mode Setting Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-44) will appear.

(2) Select the desired measure mode by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched between "Single (single measure mode)" and "Double (replication measure mode)" each time the [∧] or [∨] key is pressed.
The Sample Incubation Ready Check Setting screen will appear.

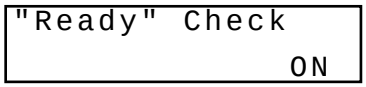


Figure 10-42: Sample Incubation Ready Check Setting Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-44) will appear.

(3) Select whether to enable the check by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched between "ON (check)" and "OFF (do not check)" each time the [∧] or [∨] key is pressed.
The Reagent Preparation Time Entry screen will appear.

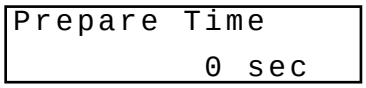


Figure: 10-43: Reagent Preparation Time Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-44) will appear.

(4) Input the time required for preparing a reagent and press the [ENTER] key.
You can input the value in the range of 0 to 99. If you do not change the value, press the [ENTER] key only. The display will return to the Measure Mode Setting screen (Figure 10-41).

(5) Press the [SELECT] key.
The Update Confirmation screen will appear.

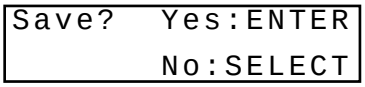


Figure 10-44: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Measure Setting Menu screen (Figure 10-3).

(6) Press the [ENTER] key.
The settings will be updated changing the status of the measure mode LED as set, and the display will return to the Measure Setting Menu screen (Figure 10-3).

3.7 Conversion Settings

Set the constant values in the conversion formula for the coagulation time of each analysis parameter.
Set "a" (a constant) and "b" (Y-intercept) in the conversion formula "y = ax + b."

CAUTION • If you change the contents of the conversion formula, correct analysis results may not be obtained. The change must be made on your own responsibility.

1. Conversion Setting Menu

When you press the [6] key on the Measure Setting Menu screen, the Conversion Setting Menu screen will appear.
You can scroll the menu up and down by using the [Λ] and [V] keys.

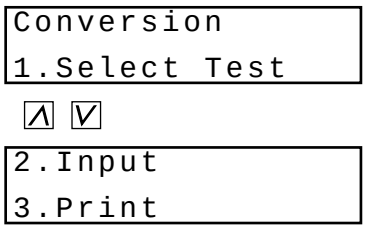


Figure 10-45: Conversion Setting Menu Screen

Pressing the following key will select each menu function.
[1] key: Moves the screen to the selection of analysis parameters (Select Test).
[2] key: Moves the screen to the conversion setting (Input).
[3] key: Prints out the contents of the conversion settings (Print).
[PRINT] key: Prints out the conversion setting menu.
[SELECT] key: Returns the screen to the measure setting menu.

2. Selecting Analysis Parameter

Select the analysis parameter for which you wish to set the conversion formula.

(1) Press the [1] key on the Conversion Setting Menu screen.
The Analysis Parameter Selection screen will appear.

Figure 10-46: Analysis Parameter Selection Screen

If you press the [SELECT] key, the display will return to the Conversion Setting Menu screen (Figure 10-45).

(2) Press the key for the desired parameter and press the [ENTER] key.
In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key.
In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key.
If you press the [IN] or [EX] key, the Factor Number Entry screen will appear.
When you press any of the other keys, the display will return to the Conversion Setting Menu screen (Figure 10-45).

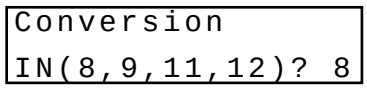


Figure 10-47: Factor Number Entry Screen

If you press the [SELECT] key, the display will return to the Analysis Parameter Selection screen (Figure 10-46).

(3) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12.
In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10.
Then press the [ENTER] key.
The display will return to the Conversion Setting Menu screen (Figure 10-45).

3. Setting Conversion Formula

Set the constant values in the conversion formula. You can input values in the range of -9.99 to 9.99 for both "a" and "b."

(1) Press the [2] key on the Conversion Setting Menu screen.
The Conversion Formula Entry screen will appear.

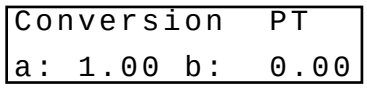


Figure 10-48: Conversion Formula Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-49) will appear.

(2) Input the value for "a" and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.

(3) Input the value for "b" and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
If you press the [SELECT] key, the Update Confirmation screen (Figure 10-49) will appear.

```
Save?  Yes:ENTER
       No:SELECT
```

Figure 10-49: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Conversion Setting Menu screen (Figure 10-45).

(4) Press the [ENTER] key.
The settings will be updated and the display will return to the Conversion Setting Menu screen (Figure 10-45).

4. Printing Out Conversion Settings

Print out the contents of the conversion settings.

(1) Press the [3] key on the Conversion Setting Menu screen.
The Printing screen will appear and the printout of the conversion settings will start. When the printout is completed, the display will return to the Conversion Setting Menu screen (Figure 10-45).

```
   Printing
  Quit:SELECT
```

Figure 10-50: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Conversion Setting Menu screen (Figure 10-45).

```
15/06/1999              09:00

DATA CONVERSION
PT       Y = 1.00X + 0.00
APTT     Y = 1.00X + 0.00
Fbg      Y = 1.00X + 0.00
TTO      Y = 1.00X + 0.00
NT       Y = 1.00X + 0.00
TT       Y = 1.00X + 0.00
F8       Y = 1.00X + 0.00
F9       Y = 1.00X + 0.00
F11      Y = 1.00X + 0.00
F12      Y = 1.00X + 0.00
F2       Y = 1.00X + 0.00
F5       Y = 1.00X + 0.00
F7       Y = 1.00X + 0.00
F10      Y = 1.00X + 0.00
```

Figure 10-51: Printout Example of Conversion Settings

4. I/O SETTINGS

Set the interface conditions for the host computer connected to the CA-50, and printout conditions for the built-in printer.

4.1 I/O Setting Menu

When you press the [2] key on the Setting Menu screen, the I/O Setting Menu screen will appear.
You can scroll the menu up and down by using the [Λ] and [V] keys.

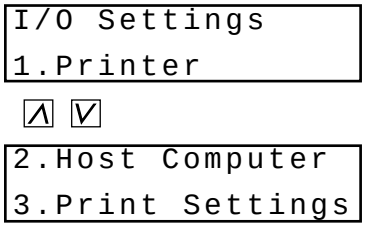


Figure 10-52: I/O Setting Menu Screen

Pressing the following key will select each menu function.
[1] key: Moves the screen to the built-in printer setting (Printer).
[2] key: Moves the screen to the host computer setting (Host Computer).
[3] key: Prints out the contents of the I/O settings (Print Settings).
[PRINT] key: Prints out the I/O setting menu.
[SELECT] key: Returns the screen to the setting menu.

4.2 Built-In Printer Settings

Set the printout condition and printout format for the built-in printer.

(1) Press the [1] key on the I/O Setting Menu screen.
The Auto Printout Selection screen will appear.

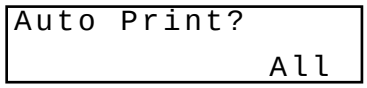


Figure 10-53: Auto Printout Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-55) will appear.

(2) Select the desired printout condition by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched between "All (Print out all analysis results when analysis is completed)" and "Err only (Print out analysis results only when an error occurs)" each time the [∧] or [∨] key is pressed.
The Printout Format Selection screen will appear.

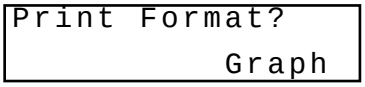


Figure 10-54: Printout Format Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-55) will appear.

(3) Select the desired printout format by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched in the order of "List", "Graph", "Analysis", "AutoList", and "Auto" each time the [∨] key is pressed.

- List : Prints out the date of analysis, ID number, coagulation time, calculation data, channel number, and error message.
- Graph : Prints out a coagulation curve in addition to the contents of "List."
- Analysis : Prints out analysis data in addition to the contents of "Graph."
- AutoList : Prints out a "List" in the ordinary case. If there is an abnormality in the coagulation curve, print out an "Analysis" automatically.
- Auto : Prints out a "Graph" in the ordinary case. If there is an abnormality in the coagulation curve, print out an "Analysis" automatically.

(4) Press the [SELECT] key.
The Update Confirmation screen will appear.

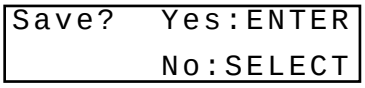


Figure 10-55: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the I/O Setting Menu screen (Figure 10-52).

(5) Press the [ENTER] key.
The settings will be updated and the display will return to the I/O Setting Menu screen (Figure 10-52).

4.3 Host Computer Settings

Set the interface conditions for the host computer.
Parameters that can be set are as shown below. For detailed data on the transmission from the host computer, see *Appendix B.*

Table 10-1: Host Computer Setting Parameters

Parameter	Selections	Default
Connection	Yes/No	No
Baud rate	1200/2400/4800/9600 (bps)	2400
Character length	7/8 (bit)	7-bit
Stop bit	1/2 (bit)	1-bit
Parity bit	Even/Odd/None	Even
Interval	0/2/3/5/7/10/15 (sec.)	2
Class	Class A/Class B	Class B

(1) Press the [2] key on the I/O Setting Menu screen.
The Connection Selection screen will appear.

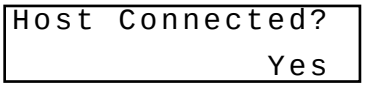


Figure 10-56: Connection Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-63) will appear.

(2) Select whether to output analysis results to the host computer by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched between "Yes (Transmit analysis results to the host computer)" and "No (Do not transmit)" each time the [∧] or [∨] key is pressed.
The Baud Rate Selection screen will appear.

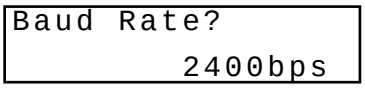


Figure 10-57: Baud Rate Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-63) will appear.

(3) Select the desired baud rate by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched in the order of "1200", "2400", "4800", and "9600" each time the [∨] key is pressed.
The Character Length Selection screen will appear.

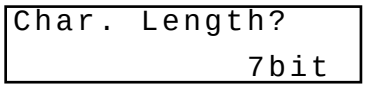


Figure 10-58: Character Length Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-63) will appear.

(4) Select the desired character length by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched between "7" and "8" each time the [∧] or [∨] key is pressed.
The Stop Bit Selection screen will appear.

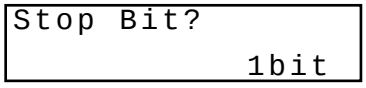


Figure 10-59: Stop Bit Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-63) will appear.

(5) Select the desired stop bit by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched between "1bit" and "2bit" each time the [∧] or [∨] key is pressed.
The Parity Bit Selection screen will appear.

Figure 10-60: Parity Bit Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-63) will appear.

(6) Select the desired parity bit by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched in the order of "Even", "Odd", and "None" each time the [∨] key is pressed.
The Interval Selection screen will appear.

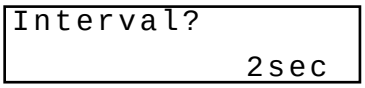


Figure 10-61: Interval Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-63) will appear.

(7) Select the desired interval by using the [∧] and [∨] keys, and press the [ENTER] key.
The display will be switched in the order of "0", "2", "3", "5", "7", "10", and "15" each time the [∨] key is pressed.
The Class Selection screen will appear.

Figure 10-62: Class Selection Screen

If you press the [ENTER] key, the display will return to the Connection Selection screen (Figure 10-56).

(8) Select the desired class by using the [∧] and [∨] keys, and press the [SELECT] key.
The display will be switched between "ClassA (One-way transmission to the host computer)" and "ClassB (Receive the response from the host computer for each text)" each time the [∧] or [∨] key is pressed.
The Update Confirmation screen will appear.

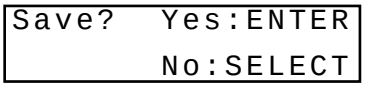


Figure 10-63: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the I/O Setting Menu screen (Figure 10-52).

(9) Press the [ENTER] key.
The settings will be updated and the display will return to the I/O Setting Menu screen (Figure 10-52).

4.4 Printing Out I/O Settings

Print out the contents of the I/O settings.

(1) Press the [3] key on the I/O Setting Menu screen.
The Printing screen will appear and the printout of the I/O settings will start. When the printout is completed, the display will return to the I/O Setting Menu screen (Figure 10-52).

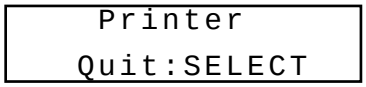


Figure 10-64: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the I/O Setting Menu screen (Figure 10-52).

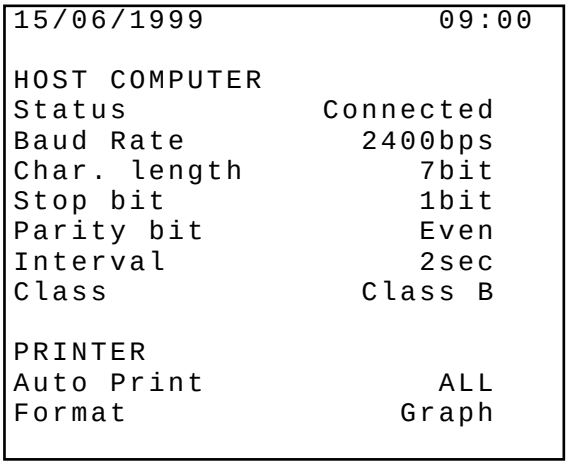


Figure 10-65: Printout Example of I/O Settings

5. SYSTEM SETTINGS

Set the parameters relating to the overall CA-50 system.

5.1 System Setting Menu

When you press the [3] key on the Setting Menu screen, the System Setting Menu screen will appear.
You can scroll the menu up and down by using the [Λ] and [V] keys.

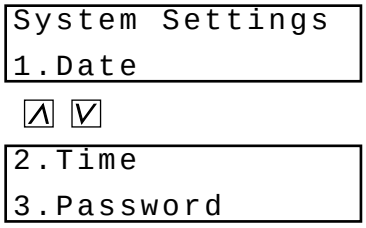


Figure 10-66: System Setting Menu Screen

Pressing the following key will select each menu function.
[1] key: Moves the screen to the date setting (Date).
[2] key: Moves the screen to the time setting (Time).
[3] key: Moves the screen to the password setting (Password).
[PRINT] key: Prints out the system setting menu.
[SELECT] key: Returns the screen to the setting menu.

5.2 Date Settings

Set the present date.

(1) Press the [1] key on the System Setting Menu screen.
The Date Setting screen will appear.

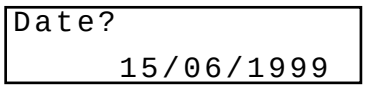


Figure 10-67: Date Setting Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-68) will appear.

(2) Input the present date and press the [ENTER] key.
The year must be inputted in 4 digits. If you input values out of the allowed range, the display will return to the original date even if the [ENTER] key is pressed.
The Update Confirmation screen will appear.

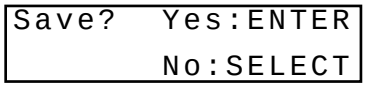


Figure 10-68: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the System Setting Menu screen (Figure 10-66).

(3) Press the [ENTER] key.
The setting will be updated and the display will return to the System Setting Menu screen (Figure 10-66).

5.3 Time Settings

Set the present time.

(1) Press the [2] key on the System Setting Menu screen.
The Time Setting screen will appear.

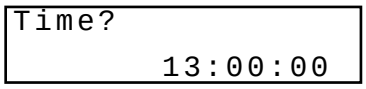


Figure 10-69: Time Setting Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-70) will appear.

(2) Input the present time and press the [ENTER] key.
The time must be inputted in the form of "hour:minute:second" and in the 24-hour form. If you input values out of the allowed range, the display will return to the original time even if the [ENTER] key is pressed.
The Update Confirmation screen will appear.

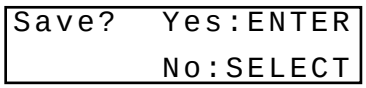


Figure 10-70: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the System Setting Menu screen (Figure 10-66).

(3) Press the [ENTER] key.
The setting will be updated and the display will return to the System Setting Menu screen (Figure 10-66).

5.4 Password Settings

Set the password.

NOTE:
- Important menus can be protected by a password to ensure that they are executed under the management of the person responsible for the instrument.
  When you try to use the menu that is protected by a password, the Password Entry screen will appear. If you enter the preset password and press the [ENTER] key, the menu will appear on the screen.
  For the menus that can be protected by a password, see *Chapter 1, Section 12: MENU TREE.*

(1) Press the [3] key on the System Setting Menu screen.
When a password has already been set, the Password Entry screen will appear.
If you have not set a password, the Password Setting screen will appear. In this case, go to step (3).

Figure 10-71: Password Entry Screen

If you press the [SELECT] key, the display will return to the System Setting Menu screen (Figure 10-66).

NOTE:
- The password displayed on the screen is masked with "*" symbols. This is for preventing other people from seeing the password when it is being entered.

(2) Input the present password and press the [ENTER] key.
If the inputted password is correct, the Password Setting screen will appear.

Figure 10-72: Password Setting Screen

If you press the [SELECT] key, the display will return to the System Setting Menu screen (Figure 10-66).

(3) Input a new password and press the [ENTER] key.
The password must consist of numerals from 0 to 9 and can extend up to 12 digits.

NOTE: • When you do not wish to use a password, you can delete a password by pressing the [C] key, [0] key and then [ENTER] key.

Input the new password once again for verification and press the [ENTER] key.
If the inputted password is correct, the Update Confirmation screen will appear.
If it is incorrect, the Update Confirmation screen will not appear. You will be required to input the new password again.

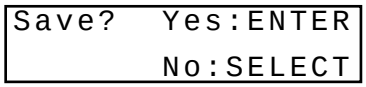


Figure 10-73: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the System Setting Menu screen (Figure 10-66).

(4) Press the [ENTER] key.
The password will be updated and the display will return to the System Setting Menu screen (Figure 10-66).

6. PRINTING OUT ALL SETTINGS

Print out the contents of all the settings excluding the password.
This also includes standard curve settings and quality control settings.

(1) Press the [4] key on the Setting Menu screen.
The Printout Confirmation screen will appear.

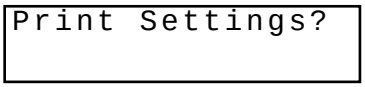


Figure 10-74: Printout Confirmation Screen

If you press the [SELECT] key, the display will return to the Setting Menu screen (Figure 10-2).

(2) Press the [ENTER] key.
The Printing screen will appear and the printout of the settings will start. When the printout is completed, the display will return to the Setting Menu screen (Figure 10-2).

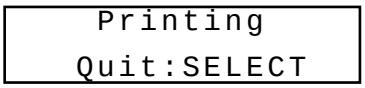


Figure 10-75: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Setting Menu screen (Figure 10-2).

NOTE: • Before starting the printout, confirm that a sufficient amount of paper is set in the printer. It takes about 13 minutes to print.

APPENDIX A: INSTALLATION

1. INTRODUCTION A-1

2. CHECK BEFORE INSTALLATION A-1

3. INSTALLATION SPACE A-2

4. CHANGING THE INSTALLATION DIRECTION OF PIPETTE GUIDE A-3

5. INSTALLING THE FILTER A-5

6. CONNECTING THE POWER CORD AND CONNECTION CORD A-5
   6.1 Connecting the Power Cord A-5
   6.2 Connecting the Connection Cord A-7

7. ADJUSTING THE LCD BRIGHTNESS A-8

8. SETTING A PRINTER PAPER A-9

1. INTRODUCTION

This product is a clinical analysis instrument. Your Sysmex service representative is responsible for unpacking, installing, and initial setup to ensure its proper and safe operation. This section will give some essential information on this instrument.

2. CHECK BEFORE INSTALLATION

Make sure that the CA-50 is free from external flaws and check the quantity of the supply parts.

Table A-1: CA-50 Unpacking Check List

Part No.	Description	Quantity			Remarks
		117V	220V	240V	
923-8092-8	Power Cord No. 15 (C-2/N. Amer)	1	0	0	
265-4731-5	Power Cord No.CS-30091	0	1	0	
265-4728-3	Power Cord No.7650	0	0	1	
266-5110-5	Fuse 250V1A ST4-0.8A-N1 (N.Amer)	2	0	0	Main Unit
266-7132-4	Fuse S504 T0.4A-T	0	2	2	Main Unit
461-2035-2	Operator's Manual CA-50 (Eng)	1	1	1	
424-1251-0	Sample Cup Conical 4 mL	20	20	20	
541-0541-8	Reaction Tube Assy (30/box)	1	1	1	
462-4841-3	Printer Paper F1-1	1	1	1	
665-8038-1	Filter CA-5D	2	2	2	
369-5029-5	Indication Mark No.1014	1	1	1	
421-9350-9	Blower Brush	1	1	1	

3. INSTALLATION SPACE

To ensure that the instrument performs to its full extent, it should be installed in an appropriate place.
Install the instrument on the flat plane.

- Select a place that is close to the power supply.
- Do not use in dusty areas.
- Saucer a place spacious enough for maintenance and service. Giving consideration to heat radiation by the instrument, keep at least 10 cm distance from the wall to the instrument's rear panel.

The instrument dimensions are shown below. The power cord is 1.8 m long.

Table A-2: Instrument Dimensions

Width (mm)	Depth (mm)	Height (mm)	Weight (kg)
327	302	113	4.5

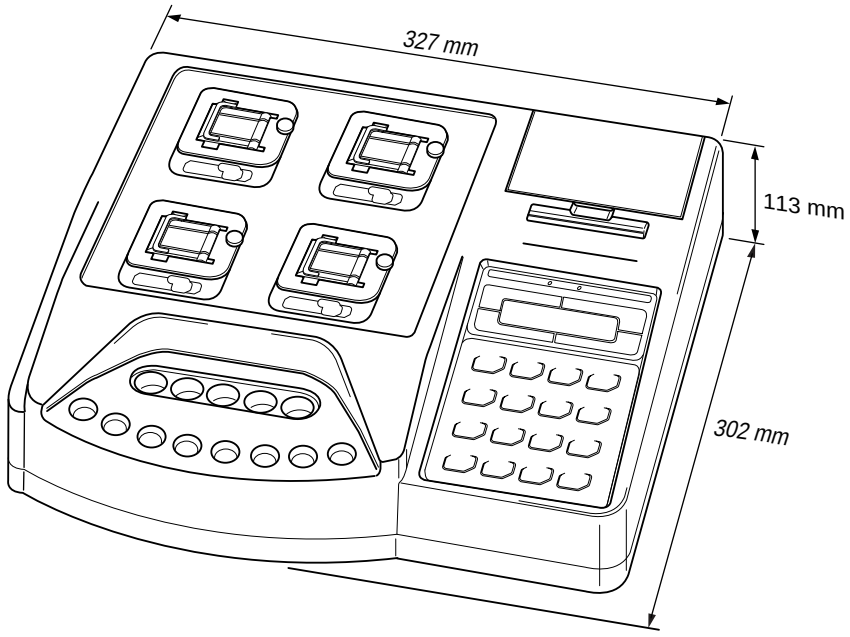


Figure A-1: Instrument Dimensions

4. CHANGING THE INSTALLATION DIRECTION OF PIPETTE GUIDE

When shipped from the factory, the pipette guide is installed so that you can hold it with your right hand. In the following cases, change the installation direction.

- When you hold the pipette by the left hand and add the reagent
- When the pipette guide is not used to add the reagent

(1) Remove the fixing screw from the pipette guide.

(2) Remove the pipette guide in the direction shown by the arrow in Figure A-2.

> **WARNING** • The fixing claw is provided with the pipette guide. Be careful not to break the claw when removing the stand.

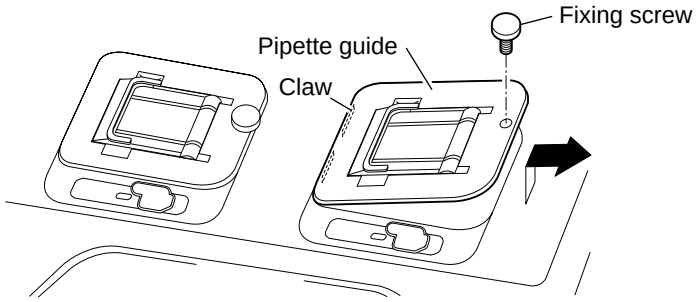


Figure A-2: Removing the Pipette guide

(3) Change the direction, and install the pipette guide.
When you hold the pipette with your left hand, install the pipette guide so that it can be opened toward the left side.
When the pipette guide is not used, install the stand so that it can be opened in the direction against you.

Install the pipette guide in the reverse order of the step (2). Hook the claw, then install the pipette guide.

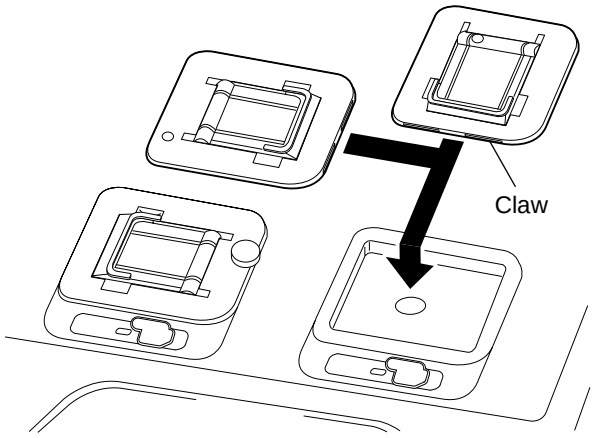


Figure A-3: Installing the Pipette guide

CAUTION
- The pipette guide also works as the detector cover. Be sure to install the pipette guide even if you add the reagent without the stand. If you do not cover it, an analysis error occurs.
- The pipette guide cannot be installed so that it can be opened toward you.

(4) Install the fixing screw.

5. INSTALLING THE FILTER

Install the filter (filter media) to prevent dust etc. from entering in the instrument at the instrument bottom air intake.

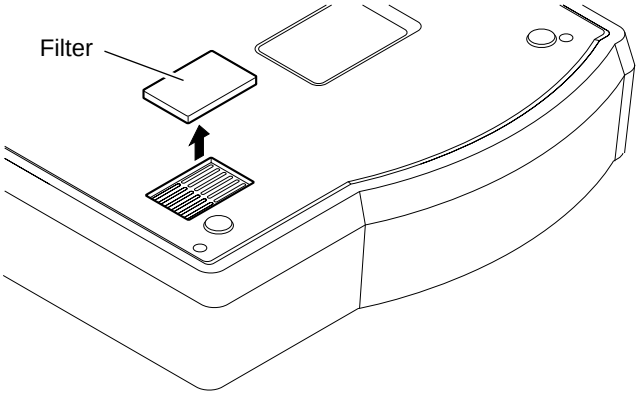


Figure A-4: Installing the Filter

6. CONNECTING THE POWER CORD AND CONNECTION CORD

Connect the power cord provided. When the output to the host computer is necessary, connect the instrument to the device with the connection cord, and carry out the setup.

6.1 Connecting the Power Cord

(1) Make sure the power switch is OFF.

WARNING • Before connecting the power cord, make sure that the power switch is OFF. Otherwise, there is a possibility of electrical shock.

(2) Connect the power cord to the power connector on the rear panel of the instrument.

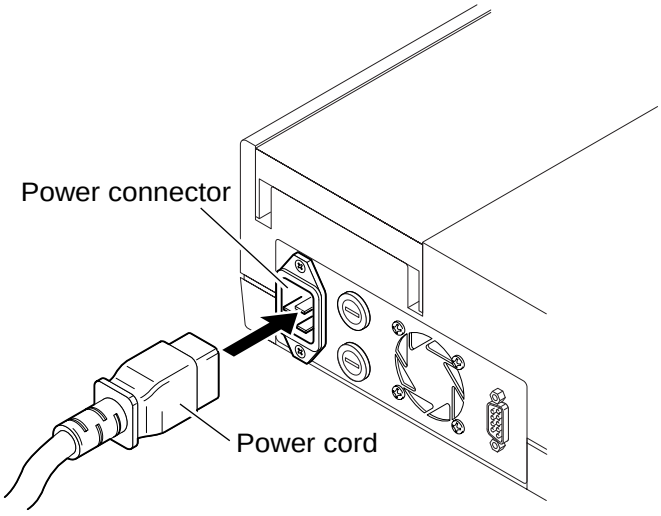


Figure A-5: Connecting the Power Cord

(3) Insert the provided power cord into a power supply outlet.
The instrument power supply cord uses a 3-prong plug. When the power supply socket is 3-prong (with grounded), simply plug it to the socket.

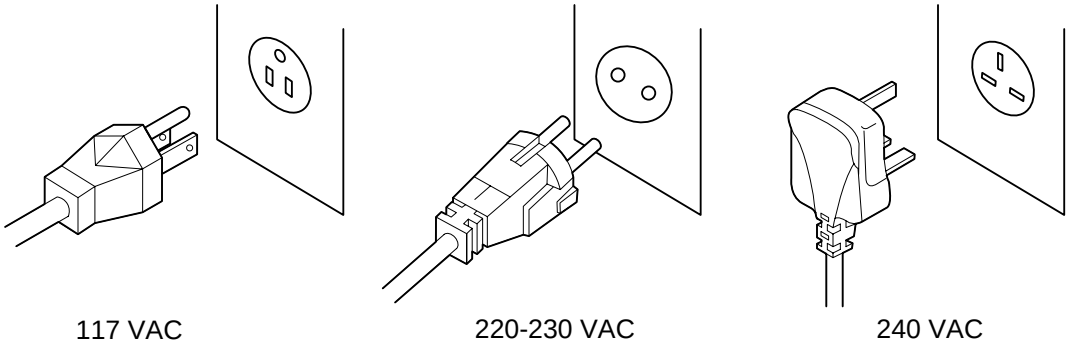


Figure A-6: Connecting with Power Supply Outlet

WARNING • Do not, for any reason, bypass the ground connection. Otherwise, there is a risk of electrical shock.

6.2 Connecting the Connection Cord

Use a connection cord matching with the host computer.
Refer to *Attachment B, Chapter 1, Section 1.1: Hardware.*

(1) Make sure the power switch is OFF.

> **CAUTION** • Before routing the connection cord, make sure the power switch is OFF. Otherwise, the unit may be damaged.

(2) Connect the instrument to the host computer using the connection cord.

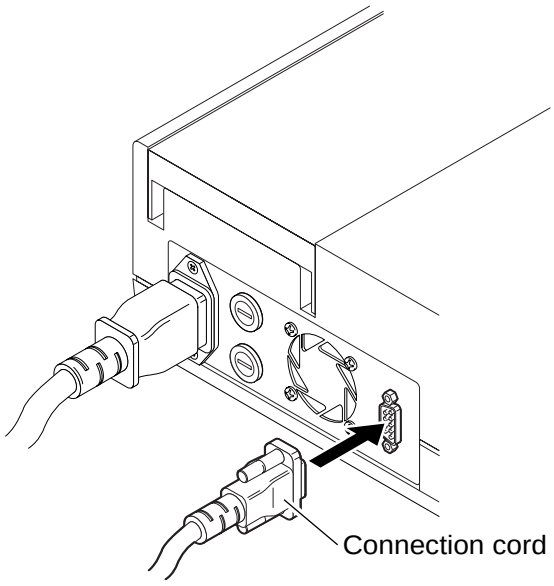


Figure A-7: Connecting the Connection Cord

(3) Perform the necessary settings for the host computer.
Refer to *Chapter 10, Section 4.3: Host Computer Settings.*

7. ADJUSTING THE LCD BRIGHTNESS

Adjust the brightness of the LCD.

(1) Turn the power switch ON.

(2) Turn the brightness control knob to adjust the brightness of characters on the LCD to a desired level.

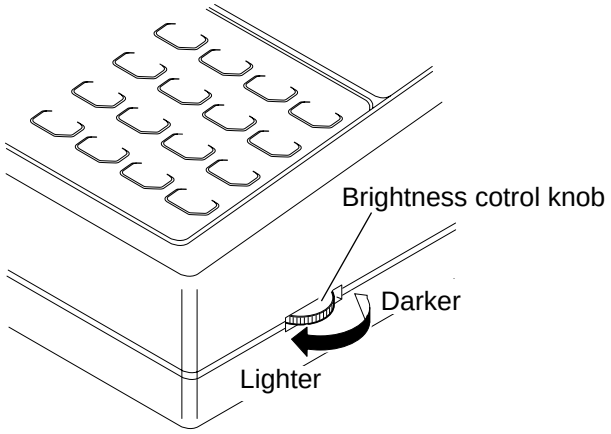


Figure A-8: Adjusting the LCD Brightness

8. SETTING A PRINTER PAPER

(1) Open the built-in printer cover.

(2) Set a printer paper, and insert the end of the paper to the built-in printer.

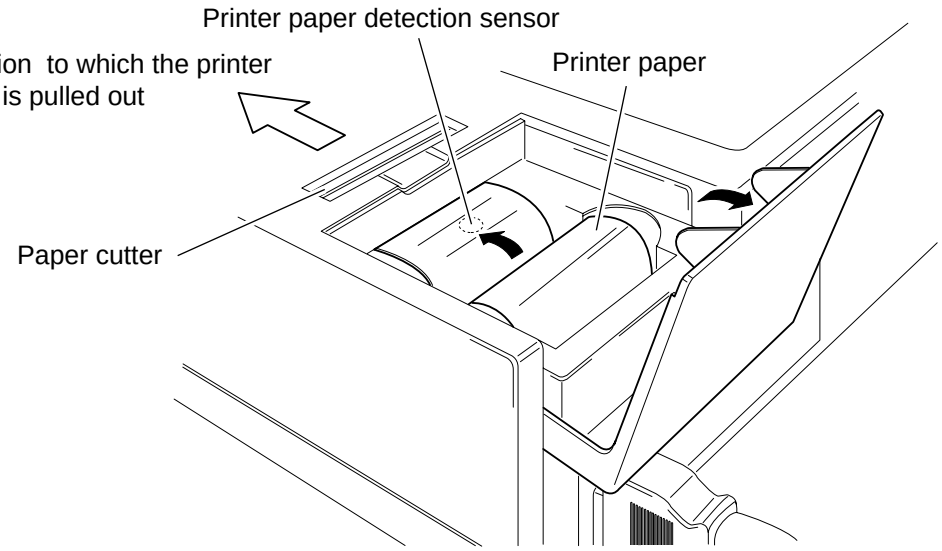


Figure A-9: Setting a Printer Paper

CAUTION:

- Insert the printer paper straight to the built-in printer. Otherwise, the paper may be caught or the life of the printer head may be shorten.
- Use a specified printer paper. Otherwise, print cannot be performed, or the paper may be caught.
  Specification: F1-1
- As for the printing side of the paper, insert the printer paper as shown in Figure A-8.
- Do not make the printer paper detection sensor dirty.
  The presence of printing paper might not be able to be detected correctly when becoming dirty. Wipe off dirt with a soft and dry cloth.
- Do not handle the printer paper by the wet hand.
  It causes paper jam.

(3) Press and hold [FEED] key until the top of the printer paper comes out of the outlet.

CAUTION:
- When there is any remained portion of the printer paper, remove the roll core from the paper roll, press the [FEED] key, and then pull the paper. At this time, pull the paper out in the direction to which the printer paper is ejected at an ordinary print operation.
- Do not pull out the paper while printing.
- When paper jam occurs while printing, turn OFF the power of the Main Unit, and remove the paper cutter by sliding it to the instrument rear side, and then remove the printer paper.
  When you install the paper cutter, push it until the click sound is heard according to the reversed procedure of removal.

APPENDIX B: TECHNICAL INFORMATION

1. OUTPUT FORMAT FOR HOST COMPUTER B-1
1.1 Hardware B-1
1.2 Software B-2
1.3 Text Format B-3

2. FACTORY DEFAULT SETTINGS B-7
2.1 QC Parameters and Factory Default Settings B-7
2.2 Standard Curve Data and Factory Default Settings B-8
2.3 Standard Curve Calculation Parameters and Factory Default Settings B-11
2.4 Instrument Setting Parameters and Factory Default Settings B-12

1. OUTPUT FORMAT FOR HOST COMPUTER

The bit serial voltage type, which conforms to the RS-232C interface, is used for host computer communication. The serial interface port for the connection with the host computer is on the rear panel of the instrument.

1.1 Hardware

1. Connector

- The connector to the host computer is located on the rear panel of the instrument.
- Use a 9-pin D-SUB, female connector.
- Fixing screws for this connector are in inch-specification.

2. Connector Signals

Table B-1: Pin Assignment

Pin No.	Signal name	Signal direction
1		
2	Receive Data (RxD)	from Host to CA-50
3	Transmit Data (TxD)	to Host from CA-50
4	Data Terminal Ready (DTR)	to Host from CA-50
5	Signal Ground (SG)	
6	Data Set Ready (DSR)	from Host to CA-50
7	Request to Send (RTS)	to Host from CA-50
8	Clear to Send (CTS)	from Host to CA-50
9		

3. Communication Format

The data is communicated in the asynchronous, half duplex mode.

Baud rate: 1200, 2400, 4800, 9600 (bps)
Code: 7 bit, 8 bit
Stop bit: 1 bit, 2 bit
Parity: None, Even, Odd
Interval: 0, 2, 3, 5, 7, 10, 15 (seconds)

4. Signal Level

Signal level conforms to JIS C6361.

Table B-2: Signal Level

Level	Data signal	Control signal
+3V or higher	Logic "0", Start bit	ON
-3V or lower	Logic "1", Stop bit	OFF

5. Interface Circuit

MAX232 (or the equivalent) is used for the interface circuit of the bit serial voltage type.

1.2 Software

1. Communication Format

1) Code

ASCII codes are used for output.

2) Structure of Text

"STX"(02 H) is sent prior to data and "ETX"(03 H) is sent at the end of data.

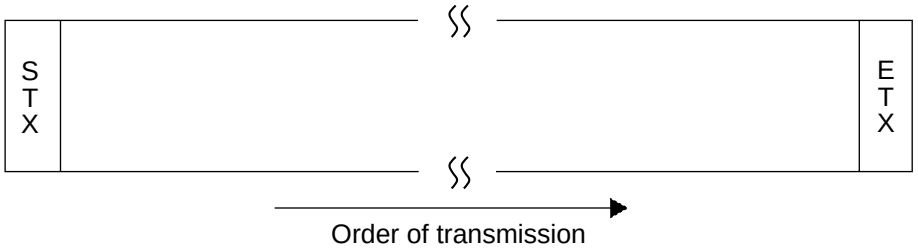


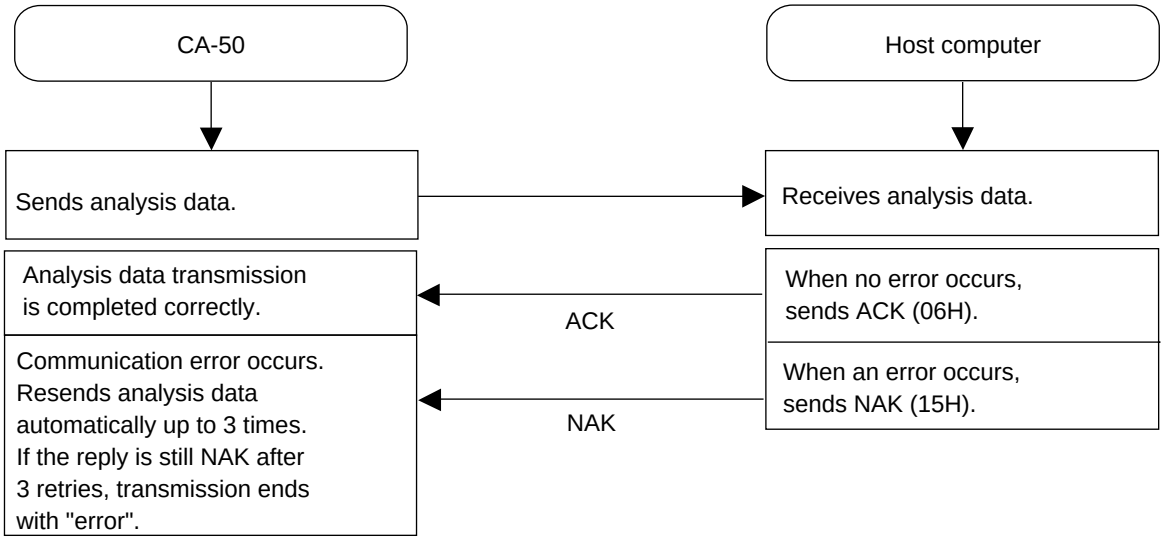
Figure B-1: Order of Transmission

3) Communication Protocol

The following two protocols are provided in the system, and can be selected according to the system status.

- **Class A**
  One-way transmission to the host computer without requiring ACK nor NAK from the host computer.
- **Class B**
  The CA-50 transmits data and then waits for ACK or NAK to complete the data transmission.

Transmission Protocol of Analysis Data


CA-50
Host computer
Sends analysis data.
Receives analysis data.
Analysis data transmission is completed correctly.
When no error occurs, sends ACK (06H).
ACK
Communication error occurs. Resends analysis data automatically up to 3 times. If the reply is still NAK after 3 retries, transmission ends with "error".
When an error occurs, sends NAK (15H).
NAK

* ACK and NAK can be arranged between STX and ETX.

Figure B-2: Analysis Data Transmission

4) Transmission Errors
If the CA-50 detects a transmission error, data transmission is interrupted and an error message is displayed on the LCD screen. Re-transmission is carried out by the operator. Transmission errors occur in the following situations.

- The control signal DSR is OFF.
- After the data is output, the control signal CTS is not turned ON within 5 seconds.
- In case of parity error, overrun error, or frame error
- When the data is transmitted, no response is sent from the host computer within 15 seconds. (Class B only)
- When the data is transmitted, other than ACK and NAK is sent from the host computer. (Class B only)
- When the data is transmitted, NAK is received 4 times. (Class B only. The CA-50 automatically re-sends the same data up to 3 times when NAK is received.)
- When the transmission initial word (STX) or ending word (ETX) is not received.

5) Transmission Interval
The transmission interval time between the data can be selected. The interval time in the case of class B means the period after receiving the response of ACK/NAK until starting the next data transmission.

1.3 Text Format

The type of communication format for the CA-50 is the analysis data text.

- **Analysis Data Text (Output)**
  The analysis data is output.
  There are two methods for output: Automatic transmission (real-time basis) after each analysis is completed, and manual transmission from the displaying detailed analysis results.

1. Analysis Data Format

Table B-3: Analysis Data Format

Parameter	No. of Characters	Example
STX	1	(02 H)
Text Distinction Code I	1	Fixed to "D"
Text Distinction Code II	1	"1" (normal data) or "2" (mean data)
Text Distinction Code III	2	Fixed to "21"
Block Number	2	Fixed to "01"
Total Number of Blocks	2	Fixed to "01"
Sample Distinction Code	1	"U" (Routine analysis data), "C" (Quality control analysis data)
Date	6	"OOOOOO"
Time	4	"OOOO"
Rack Number	4	Fixed to “0000” (Not in use)
Tube Position Number	2	Fixed to “00” (Not in use)
Sample ID Number	15	(OO.... OO)
ID Information	1	"M" (Manual entry), "A" (Automatic assignment)
Reserved	11	
Analysis Parameter, Data 1	9	
Analysis Parameter, Data 2	9	
• • •	• • •	• • •
Analysis Parameter N, Data N	9	
ETX	1	(03 H)

Total: 54+N× 9 bytes

- **Order of Transmission**
  The order of transmission is from the top parameter to the bottom; the most significant digit first and the least significant digit last. Zero suppression is not performed.

- **Block Number and Total Number of Blocks**
  The analysis data is divided for transmission so that one block contains 255 or less characters.
  The block number is the sequence number of the divided text.
  The total number of blocks is the total number of divided text.
  Normally, block number and number of blocks are "01".

- **Sample Distinction Code**
  The types of analysis data are shown.
  U: Routine analysis data
  C: Quality control analysis data

- **Date and Time**
  Set the date and time when the analysis was performed. The date format conforms to the format set in the date/time setting switch. Zero suppression is not performed.

- **Sample ID Number**
  The sample ID number consists of 15 digit numerals. A hyphen "-" (2DH) may be inserted between numerals. The hyphen "-" is included in the 15 digits. Zero suppression is not performed. The most significant digits are filled with spaces (20H) if it is less than 15 digits.

- **ID Information**
  The ID information indicates the method in which the sample ID number is registered.
  M: Manual entry
  A: Automatic assignment by the instrument

- **Analysis Parameter, Data**

Table B-4: Analysis Parameter, Data

Parameter	No. of Characters	
Parameter Code	3	(OOO)
Data	5	(OOOO.O) [sec]
		(□OOO.O) [%], [mg/dL], [IU]
		(□O.OOO) [g/L]
		(□OO.OO) INR, [-]
Flag	1	"□", "+", "-", "*", "<", ">"

□ indicates a space (20 H).

1) Parameter Code

Table B-5: Parameter Code

04x: PT	05x: APTT	06x: Fbg
08x: TTO	09x: NT	51x: TT
12x: Factor II	15x: Factor V	17x: Factor VII
18x: Factor VIII	19x: Factor IX	20x: Factor X
21x: Factor XI	22x: Factor XII	

Where, x is:
1: Time
2: Activity percent/concentration
3: Ratio
4: INR
5: DFbg

* Additional parameter codes may be added in the future. When the host computer receives a parameter code not mentioned above, prepare a host computer program that will ignore the data of such a parameter code.

2) Data

Because the decimal point is not transmitted, the host computer must add the appropriate decimal point specified for each parameter.
The position of decimal point varies depending on the unit.

Time:	OOOO.O	→	OOOOO (*1)
Activity percent:	OOO.O	→	□OOOO (*2)
PT ratio:	OO.OO	→	□OOOO (*2)
INR:	OO.OO	→	□OOOO (*2)
Fbg concentration:	□OOO.O	→	□OOOO (*2)

□ indicates a space (20 H).

1. If coagulation time cannot be obtained such as in the case of an analysis error, "" is entered instead of "O" for the number of characters. However, "/" is entered in the case of mean data.

*2. If data cannot be calculated in cases when the standard curve is not set or the coagulation time is not obtained, "-" is entered instead of "O" for the number of characters. And if the data cannot be calculated due to no coagulation time being obtained in cases of instrument error, space (20 H) is entered instead of "O" for the number of characters. If the number of digits for the calculation data exceeds the specification, "+" is entered.

3) Flags

*	Analysis error occurred, disparate data of mean data occurred.
<	Over the upper report limit
>	Under the lower report limit
+	Over the upper mark limit
-	Under the lower mark limit
space:	No error

2. FACTORY DEFAULT SETTINGS

2.1 QC Parameters and Factory Default Settings

Table B-6: QC Parameters and Factory Default Settings

		Factory Default Settings							
		PT	APTT	Fbg	TTO	NT	TT	Intrinsic Factor	Extrinsic Factor
Parameter	Sec/Conc./ Ratio/INR/DFbg (*1)	%	sec	mg/dL	%	%	sec	%	%
Upper Limit	0 - 9999 (*2)	0	0	0	0	0	0	0	0
Target Value	0 - 9999 (*2)	0	0	0	0	0	0	0	0
Lower Limit	0 - 9999 (*2)	0	0	0	0	0	0	0	0

*1 Can be selected from the coagulation time or the calculation parameters. (However, parameters which are set to OFF in the standard curve calculation parameter settings cannot be selected.)

*2 The numerals of 4 digits are displayed, and the position of the decimal point varies depending on the selected parameter.

2.2 Standard Curve Data and Factory Default Settings

Table B-7: Standard Curve Data and Factory Default Settings

		Activity % or Concentration	Coagulation Time	Remarks
PT	STD1	100.0	0.0	Cannot be set when activity percent is OFF.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	0.0	0.0	
	STD5	0.0	0.0	
	STD6	0.0	0.0	
	Normal	0.0	-	Can be set only when ratio or INR is ON.
	ISI	0.0	-	Can be set only when INR is ON.
	DFbg	0.0	-	Can be set only when DFbg is ON.
	dH	0	-	Can be set only when DFbg is ON.
APTT	STD1	100.0	0.0	Can be set only when activity percent is ON.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	0.0	0.0	
	STD5	0.0	0.0	
	STD6	0.0	0.0	
Fbg	STD1	400.0	0.0	Cannot be set when concentration is OFF.
	STD2	200.0	0.0	
	STD3	100.0	0.0	
	STD4	0.0	0.0	
	STD5	0.0	0.0	
	STD6	0.0	0.0	
TTO	STD1	100.0	0.0	Cannot be set when activity percent is OFF.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	12.5	0.0	
	STD5	6.3	0.0	
	STD6	0.0	0.0	
	Normal	0.0	-	Can be set only when ratio or INR is ON.
	ISI	0.0	-	Can be set only when INR is ON.
NT	STD1	100.0	0.0	Cannot be set when activity percent is OFF.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	12.5	0.0	
	STD5	6.3	0.0	
	STD6	0.0	0.0	
	Normal	0.0	-	Can be set only when ratio or INR is ON.
	ISI	0.0	-	Can be set only when INR is ON.

		Activity % or Concentration	Coagulation Time	Remarks
TT	STD1	100.0	0.0	Can be set only when activity percent is ON.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	12.5	0.0	
	STD5	6.3	0.0	
	STD6	0.0	0.0	
F8	STD1	100.0	0.0	Cannot be set when activity percent is OFF.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	12.5	0.0	
	STD5	6.3	0.0	
	STD6	0.0	0.0	
F9	STD1	100.0	0.0	Cannot be set when activity percent is OFF.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	12.5	0.0	
	STD5	6.3	0.0	
	STD6	0.0	0.0	
F11	STD1	100.0	0.0	Cannot be set when activity percent is OFF.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	12.5	0.0	
	STD5	6.3	0.0	
	STD6	0.0	0.0	
F12	STD1	100.0	0.0	Cannot be set when activity percent is OFF.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	12.5	0.0	
	STD5	6.3	0.0	
	STD6	0.0	0.0	
F2	STD1	100.0	0.0	Cannot be set when activity percent is OFF.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	12.5	0.0	
	STD5	6.3	0.0	
	STD6	0.0	0.0	

		Activity % or Concentration	Coagulation Time	Remarks
F5	STD1	100.0	0.0	Cannot be set when activity percent is OFF.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	12.5	0.0	
	STD5	6.3	0.0	
	STD6	0.0	0.0	
F7	STD1	100.0	0.0	Cannot be set when activity percent is OFF.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	12.5	0.0	
	STD5	6.3	0.0	
	STD6	0.0	0.0	
F10	STD1	100.0	0.0	Cannot be set when activity percent is OFF.
	STD2	50.0	0.0	
	STD3	25.0	0.0	
	STD4	12.5	0.0	
	STD5	6.3	0.0	
	STD6	0.0	0.0	

2.3 Standard Curve Calculation Parameters and Factory Default Settings

Table B-8: Standard Curve Calculation Parameters and Factory Default Settings

Analysis Parameter	Parameter	ON/OFF	Unit	Calculation Method
PT	Activity	ON	%	Log. Pt Pt
	Ratio	ON	-	-
	INR	ON	-	-
	DFbg	OFF	mg/dL	Lin. Regress
APTT	Activity	OFF	%	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-
Fbg	Conc.	ON	mg/dL	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-
TTO	Activity	ON	%	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-
NT	Activity	ON	%	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-
TT	Activity	OFF	%	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-
F8	Activity	ON	%	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-
F9	Activity	ON	%	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-
F11	Activity	ON	%	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-
F12	Activity	ON	%	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-
F2	Activity	ON	%	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-
F5	Activity	ON	%	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-
F7	Activity	ON	%	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-
F10	Activity	ON	%	Log. Pt Pt
	Ratio	OFF	-	-
	INR	OFF	-	-

2.4 Instrument Setting Parameters and Factory Default Settings

Table B-9: Instrument Setting Parameters and Factory Default Settings

Parameter		Range	Factory Default Settings							
			PT	APTT	Fbg	TTO	NT	TT	Intrinsic Factor	Extrinsic Factor
Test Protocol	Coagulation Detection Point	2 - 80 (%)	50	50	50	50	50	50	50	50
	Maximum Detection Time	100 - 600 (sec)	100	190	100	190	190	190	190	190
	Sensitivity	High/Low Sensitivity	Low	Low	High	High	High	Low	Low	Low
	1st Reagent Addition Time	0 - 999 (sec)	180	60	180	180	180	120	60	180
	1st Reagent Addition Allowed Time (First)	0 - 99 (sec)	5	5	5	5	5	5	5	5
	1st Reagent Addition Allowed Time (Second)	0 - 99 (sec)	5	5	5	5	5	5	5	5
	2nd Reagent Addition Time	0 - 999 (sec)	-	240	-	-	-	-	240	-
	2nd Reagent Addition Allowed Time (Before)	0 - 99 (sec)	5	5	5	5	5	5	5	5
	2nd Reagent Addition Allowed Time (After)	0 - 99 (sec)	5	5	5	5	5	5	5	5
Mark Limits	Data Check Parameter	Sec/Conc./Ratio/ INR (*1)	%	sec	mg/dL	%	%	sec	%	%
	Upper Limit	0 - 9999 (*2)	0	0	0	0	0	0	0	0
	Lower Limit	0 - 9999 (*2)	0	0	0	0	0	0	0	0
Report Limits	Upper Limit	0 - 9999 (*2)	0	0	450	0	0	0	0	0
	Lower Limit	0 - 9999 (*2)	0	0	50	0	0	0	0	0
Replication Difference Limits		0 - 999 (%)	20	20	20	20	20	20	20	20

*1 Can be selected from the coagulation time or the calculation parameters.
*2 The numerals of 4 digits are displayed, and the position of the decimal point varies depending on the selected parameter. (However, parameters which are set to OFF in the standard curve calculation parameter settings cannot be selected.)

Parameter		Selections	Factory Default Settings
Measure Mode		Single/Double	Single
Sample Incubation Ready Check		ON/OFF	ON
Reagent Preparation time		Any numeral of 0 - 99 (sec)	0
Host Computer	Connection Status	Connected/Do not connect	Do not connect
	Baud Rate	1200/2400/4800/9600 (bps)	2400
	Character Length	7-bit/8-bit	7-bit
	Stop Bit	1-bit/2-bit	1-bit
	Parity Bit	Even/Odd/None	Even
	Interval	0/2/3/5/7/10/15 (sec)	2
	Class	Class A/Class B	Class B
Built-in Printer	Auto Print	All/Err only	All
	Format	List/Graph/Analysis/Auto List/Auto	Graph
Date	Year	Numeral of 4 digits	
	Month	Any numeral of 1 - 12	
	Day	Any numeral of 1 - 31	
Time	Hour	Any numeral of 0 - 23	
	Minute	Any numeral of 0 - 59	
	Second	Any numeral of 0 - 59	

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